IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

UNITED STATES ex rel. CHESTER SALDIVAR, Plaintiff, v. FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA Defendant.	:	CIVIL ACTION NO. 1:10-CV-1614-AT

ORDER

This qui tam action arises out of allegations that Defendant Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America ("Fresenius" or "FMCNA") violated the False Claims Act ("FCA"), 31 U.S.C. § 3729, on a regular basis when it submitted requests for reimbursement for lucrative dialysis drugs that it received for free. Relator Chester Saldivar alleges that Fresenius billed Medicare for administration of overfill — a varying amount of extra medicine contained in individual vials the purpose of which is to facilitate extraction of the labeled amount on the vial. The Court previously held, that because overfill did not represent a cost incurred by Fresenius, Fresenius's overfill billing practices were impermissible under the applicable Medicare rules

and regulations from 2006 through 2010. Thus, billing for overfill during this time constituted a "false claim" under the FCA.

However, to prevail on an FCA claim, Relator must also prove that Fresenius knowingly submitted the false claims. Under the FCA, "knowingly" "means that a person, with respect to information (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A).

The parties have filed cross-motions for summary judgment addressing this additional element of Relator's FCA claim [Docs. 217, 221]. After a thorough review of the extensive record, and with the benefit of oral argument, the Court **GRANTS** Fresenius's motion [Doc. 221] and **DENIES** Relator's motion [Doc. 217]. Although the record contains some evidence that Fresenius had the necessary information at its disposal to deduce that billing for overfill was impermissible, there is no evidence that Fresenius actually knew that billing for administered overfill was impermissible, and insufficient evidence from which a reasonable jury could find Fresenius acted with deliberate ignorance or reckless disregard as to the impermissibility of billing for administered overfill.

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I. LEGAL STANDARD

The Court may grant summary judgment only if the record shows "that there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A factual dispute is genuine if there is sufficient evidence for a reasonable jury to return a verdict in favor of the non-moving party. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A factual dispute is material if resolving the factual issue might change the suit's outcome under the governing law. *Id.* The motion should be granted only if no rational fact finder could return a verdict in favor of the non-moving party. *Id.* at 249.

When ruling on the motion, the Court must view all the evidence in the record in the light most favorable to the non-moving party and resolve all factual disputes in the non-moving party's favor. *See Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000). The moving party need not positively disprove the opponent's case; rather, the moving party must establish the lack of evidentiary support for the non-moving party's position. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). If the moving party meets this initial burden, in order to survive summary judgment, the non-moving party must then present competent evidence beyond the pleadings to show that there is a genuine issue for trial. *Id.* at 324-26. The essential question is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-

sided that one party must prevail as a matter of law." *Anderson*, 477 U.S. at 251-52.

The standard of review for cross-motions for summary judgment does not differ from the standard applied when only one party files a motion, but simply requires a determination of whether either of the parties deserves judgment as a matter of law on the facts that are not disputed. *Am. Bankers Ins. Group v. United States*, 408 F.3d 1328, 1331 (11th Cir. 2005). The Court must consider each motion on its own merits, resolving all reasonable inferences against the party whose motion is under consideration. *Id.* The Eleventh Circuit has explained that "[c]ross-motions for summary judgment will not, in themselves, warrant the court in granting summary judgment unless one of the parties is entitled to judgment as a matter of law on facts that are not genuinely disputed." *United States v. Oakley*, 744 F.2d 1553, 1555 (11th Cir. 1984). Cross-motions may, however, be probative of the absence of a factual dispute where they reflect general agreement by the parties as to the controlling legal theories and material facts. *Id.* at 1555-56.

II. OVERVIEW[1]

To contextualize the instant cross-motions for summary judgment addressing Fresenius's corporate intent, the Court provides an overview of the factual and legal background of this case. The Court begins first with a general description of the drugs at issue — epoten alpha, commercially sold as Epogen®, ("Epogen" or "EPO"), and paricalcitrol (a Vitamin D supplement), commercially sold as Zemplar® ("Zemplar") — and Fresenius's practice of utilizing, administering and billing Medicare for overfill of these drugs. The Court then briefly describes the most relevant Medicare reimbursement rules applicable to the administration of these drugs by facilities such as Fresenius. The Court next highlights the 2011 Centers for Medicare & Medicaid Services ("CMS") rule,

[1] The Court derives the facts in this Order from the parties' statements of undisputed material facts to the extent such facts were not meaningfully objected to, and otherwise derives the facts from the record. Relator's objection to about 80% of Fresenius's factual statements is the same: that the statement of fact is not material and, by including so many immaterial facts, the statement of material facts fails to comply with Local Rule 56.1(B)(1). (*See, e.g.*, Relator Resp. Def. Statement of Undisputed Material Facts ("Relator Resp. Def. SUMF") Nos. 1-43, 45-53, 64, 67-68, etc., Doc. 231.) Under Local Rule 56.1(B)(1), a statement of material facts must be concise. LR 56.1(B)(1), NDGa. Fresenius's Statement of Undisputed Material Facts ("SUMF", Doc. 221-2) is far from concise, topping 740 paragraphs in nearly 180 pages. Nonetheless, many of the statements contained in Fresenius's SUMF are in fact material, or at the very least, essential to understanding the full context of the parties' motion for summary judgment. And Relator does not object on a substantive basis to most of these statements of fact. Relator does not contend that Fresenius's record citations do not support Fresenius's factual statements. Under Local Rule 56.1(B)(2), "[t]he court will deem the movant's citations [in its statement of material facts] supportive of its facts unless the respondent specifically informs the court to the contrary in the response." LR 56.1(B)(2), NDGa. And in most of the instances in which Relator objects on a substantive basis, Relator simply summarizes the Court's previous order on the parties' cross-motions for summary judgment, asserts that "Fresenius at all times understood these rules," and refers the Court to paragraphs 11 through 56 of his own SUMF. The Court has no obligation to scour the record on a motion for summary judgment. *See Tomasini v. Mt. Sinai Med. Ctr. of Fla.*, 315 F. Supp. 2d 1252, 1260 n.11 (S.D. Fla. 2004). Thus, to the extent the Court finds facts in Fresenius's SUMF helpful to the overall context of this case, and to the extent Relator does not object on a substantive basis, the Court adopts these facts to place this case in its factual and procedural context. (*See, e.g.*, Def. SUMF ¶¶ 1-18 (providing background on the use of Epogen and Zemplar at dialysis facilities).) The Court provides citations to the record where the factual statement is substantively contested or where it would be particularly helpful.

which retrospectively announced that overfill had not been reimbursable under the Medicare rules since at least 2006 and prospectively, expressly prohibited billing for overfill starting January 1, 2011. The Court finally summarizes this Court's previous decision that, consistent with CMS's retrospective explanation of the Medicare landscape, overfill administration was not reimbursable from 2006 through 2010.

The Court then provides a description of the factual background in Part III, starting with a summary of the direct evidence of Fresenius's corporate knowledge, including testimony of Fresenius's executives and attorneys. The Court then dives into the record, detailing, for example, evidence of Office of Inspector General ("OIG") and CMS reports addressing Epogen or Zemplar and related overfill issues, government investigations and other qui tam actions involving overfill, communications between Fresenius and government officials, Fresenius internal communications regarding overfill and concerns that at least one Medicare fiscal intermediary may have considered prohibiting billing for administered overfill, and testimony of CMS Rule 30(b)(6) representatives and the parties' proffered experts.

Part IV addresses Fresenius's Motion for Summary Judgment, concluding that, based on this record, no reasonable jury could find that Fresenius acted recklessly regarding its overfill billing practices. Part V the briefly rejects Relator's argument raised in his Motion for Partial Summary Judgment.

A. Epogen and Zemplar Use

Fresenius is the country's largest owner of outpatient renal dialysis facilities. Fresenius's patients suffer from chronic renal failure that has advanced to End Stage Renal Disease ("ESRD"). As part of their treatment, these ESRD patients often require hemodialysis. Hemodialysis uses artificial methods to clean and filter the blood. In connection with this ESRD treatment, physicians often prescribe ESRD patients intravenous drugs, including the two at issue in this case, epoten alpha, commercially sold as Epogen, and paricalcitrol, commercially sold as Zemplar. Fresenius's nurses then administer these drugs at an outpatient dialysis facility by injecting them through syringes inserted into plastic blood lines (tubing) that are connected to patients' vascular access points. For patients covered by Medicare, Fresenius then submits a request for reimbursement to Medicare for the provision of these drugs.

Manufacturers of Epogen and Zemplar distribute the drugs in individual vials with the amount of drug contained in the vial labeled on the vial itself. However, consistent with industry standards and federal regulations, the manufacturers also include in each vial a surplus volume of each drug, referred to as "overfill." For example, a 5-unit vial of Zemplar may, in fact, contain 6 units of the drug. This overfill ensures that the nurses administering the drug will be able to extract at least the labeled amount from the vial. The amount of overfill is determined by the manufacturer and can vary, but this amount is not included in the amount appearing on the drug's label.

ESRD drugs generally come in two types of vials: single-use and multi-use. Despite the name, single-use vials have not historically been limited to a single use. Under certain conditions, providers have been authorized to reenter single-use vials in order to capture contents, including overfill, not initially extracted and then administer the contents to patients. This ability to reenter single-use and multi-use vials allows providers to minimize waste. For example, depending on the amount of drug contained in the vials and the prescribed amount to administer to individual patients, nurses do not always extract all of the available drug from the vial to administer one dose of the drug. If the nurse is prohibited from reentering the vial a second time to extract the remaining drug, then the remaining drug is wasted. Thus, to avoid waste, providers have in the past had an incentive to reenter vials and extract the remaining medicine.

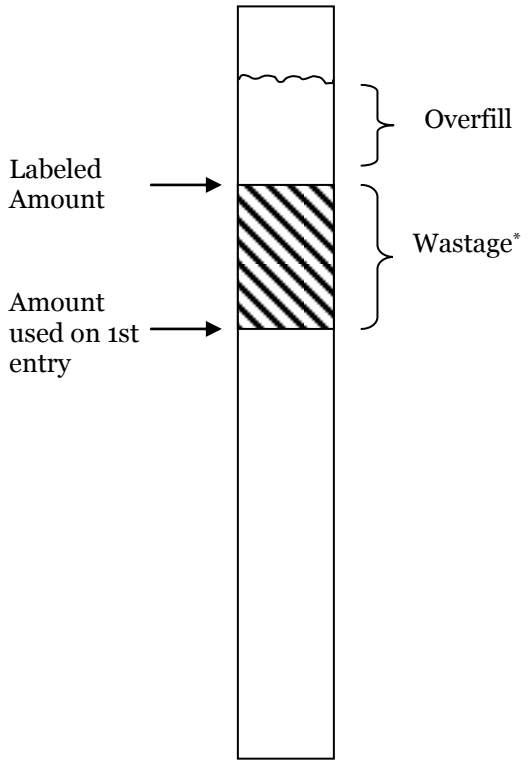
Fresenius and other dialysis centers have routinely, lawfully reentered single-use vials of both Epogen and Zemplar and multi-use vials of Epogen in order to extract and administer all contents to patients, including overfill.[2] For example, in the early 1990s, dialysis facilities were regularly reentering single-use vials of Epogen in order to minimize waste and maximize profits. The Office of Inspector General ("OIG") and the predecessor agency to the Centers for Medicare & Medicaid Services ("CMS") were aware of this widespread, industry practice.

[2] Epogen has been sold in single-use vials, and from 2004 through 2010, in both single-use and multi-use vials. Zemplar has only been sold in single-use vials during the relevant time period. Beginning in 2008, providers were no longer authorized to reenter single-use vials.

While at certain times providers were legally allowed to reenter single-use vials, providers could also receive reimbursement for a certain portion of unused medicine in an individual single-use vial. (*See* 2004 Medicare Claims Processing Manual, Chapter 17, Section 40, Doc. 251-1.)[3] During the relevant time period, Medicare reimbursed providers for the entire amount of Zemplar or Epogen as indicated on the label of the single-use vial (i.e. excluding overfill) even if the provider only utilized a portion of the contents. (*See, e.g. id.* ("[I]f a physician must discard the remainder of a vial or other package after administering it to a Medicare patient, the program covers the amount of drug discarded along with the amount administered."); Relator Ex. 33 (May 25, 2007 CMS Manual System, Pub 100-04 Medicare Claims Processing) at 5 ("[T]he program provides payment for the amount of drug or *biological* discarded along with the amount administered, *up to the amount of the drug or biological as indicated on the vial or package label*.")) In other words, Medicare would reimburse providers for not only the amount of the medication they used, but also the amount of the medication they were unable to use, up to the labeled amount. The amount of the drug remaining in the vial, up to the labeled amount on the vial, is sometimes referred to as "waste" or "wastage." To be clear, under this policy, Medicare did not reimburse providers for *overfill* (the amount of drug over the labeled

[3] The Court directed the parties to file the 2004 version of the "Discarded Drugs and Bioligicals Policy" published in the Medicare Claims Processing Manual, Chapter 17, Section 40. The Court accepts that document (Doc. 251-1) as part of the summary judgment record.

amount) that was thrown away. The following distinguishes between overfill and wastage:



One Vial of Medicine

Fresenius complied with the wastage rules and, on occasion, billed for units of wasted drug up to the labeled amount on the vial in accordance with CMS rules. Fresenius did not bill for discarded overfill. (*See* Def. Resp. Relator SUMF ¶ 36.)

On the other hand, Fresenius did bill for overfill that was not discarded. According to Fresenius's Senior Vice President and Deputy General Counsel for Litigation, Ron Castle, during the relevant time periods (2005 through 2010), Fresenius has openly, routinely, and regularly directed its nurses to utilize as

much overfill as possible. Fresenius then sought and received reimbursement from Medicare for all covered medications administered to patients, "without regard to whether some or all of the medication actually administered to particular patients can literally be attributable to the 'overfill' portion of the medication in the vial." (Def. Ex. 1 ("2011 Castle Aff.") ¶ 24.)

B. Medicare Reimbursement for Epogen and Zemplar

Before 2005, Medicare generally reimbursed providers for the provision of separately billed Part B drugs, including Epogen and Zemplar, based upon the manufacturers' Average Wholesale Price ("AWP") or a statutorily set fee schedule.[4] *See* 42 C.F.R. § 405.517; Medicare Payment Advisory Commission ("MedPAC"), Report to the Congress: Medicare Payment Policy, § 2F: Outpatient dialysis services, at 104-105 (March 2002) (hereinafter "2002 MedPAC Report).[5] The AWP prices were published in drug pricing publications but did not accurately reflect the actual costs to providers. MedPAC Report at 105 (concluding that it was "highly probable that Medicare [was paying] too much for certain injectable medications"). (*See also* Relator Ex. 9 at iii ("[I]n 2003, the 4

[4] Prior to the effective date of the Medicare Modernization Act of 2003 ("MMA") amendments to 42 U.S.C. § 1395rr, Epogen administered to ESRD patients by independent renal dialysis facilities was reimbursed on the basis of a fee schedule set in accordance with 42 U.S.C. § 13955rr(b)(11)(B), and pursuant to 42 U.S.C. § 1395rr(b)(13)(A)(i), reimbursement for Zemplar administered to ESRD patients by independent renal dialysis facilities was made on the basis of a fee schedule set at 95 percent of average wholesale price. Relator does not now contend that overfill billing was prohibited during this time because it was not clear whether AWP reimbursement took overfill into account. (*See* Relator Resp. at 10, Doc. 230.)

[5] Available at http://67.59.137.244/publications/congressional_reports/Mar02_Ch2F.pdf (last visited July 13, 2015)

largest dialysis providers paid, on average, 22 percent less than the Medicare reimbursement amount for 10 drugs.").)

To address this and similar problems, as part of the Medicare Modernization Act of 2003 ("MMA"), Congress instituted changes to the ESRD program. *See In re Pharm. Indus. Average Wholesale Price Litigation*, 460 F. Supp. 2d 277, 283 (D. Mass. 2006) (noting that Congress responded to the disconnect between the AWP and the actual price paid by purchasers by passing the MMA). In addition to increasing the composite rate of reimbursement (the rate at which Medicare reimburses for bundled dialysis services), the MMA changed the way Medicare reimbursed freestanding dialysis centers like Fresenius for the cost of separately billable drugs and biologics. Beginning in 2005, Medicare reimbursed for Epogen and Zemplar based on "acquisition cost as determined by the Inspector General report." 42 C.F.R. § 414.904(d)(2)(i). Medicare reimbursed most other Medicare Part B drugs based on the "Average Sales Price" ("ASP"). 42 U.S.C. § 1395w-3a;[6] 42 C.F.R. § 414.904. And this ASP methodology began to apply to Zemplar and Epogen furnished by dialysis facilities like Fresenius on January 1, 2006. *See* 42 U.S.C. § 1395rr(b)(13)(A)(iii); 42 C.F.R. § 414.904(d)(2)(iii).

The ASP methodology endeavored to more accurately reflect the costs of drugs to individual providers. "In simplified terms, a drug's ASP represents the manufacturer's total sales divided by the total number of units of the drug sold in

[6] This provision is the codification of Section 1847A of the Social Security Act, Pub. L. 108-173, Title III, § 303(c)(1), 117 Stat. 2239.

a quarter." *United States ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 65 (D. Mass. 2011) (citing 42 U.S.C. § 1395w-3a(c)(1)(A)-(B)). Thus, if the sales price (the numerator) increases but the total number of units sold (the denominator) stays the same, the ASP increases.

Congress delegated the task of calculating the ASP to the Secretary of Health and Human Services (the "Secretary"). *See* 42 U.S.C. §§ 1395w-3a(b)(6)(A)(i)(I), (b)(6)(B), (c)(3); 42 U.S.C. § 1395rr(b)(2)(B). To calculate the ASP, the Secretary collects data from the drug manufacturers. By statute, this data must take into account "volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1396r-8)." 42 U.S.C. § 1395w-3a(c)(3). The statute authorizes the Secretary to also "include in such price other price concessions, which may be based on recommendations of the Inspector General, that would result in a reduction of the cost to the purchaser." *Id.* During the relevant time period, the Secretary never identified overfill as a price concession that would result in a reduction of the cost to the purchaser, because accounting for overfill would be operationally infeasible. *See* 75 Fed. Reg. 73461-73471 (Nov. 29, 2010) ("[W]e have authority under section 1847A(c)(3) of the Act to identify price concessions that must be included in the ASP calculation. However, we have a practical reason for declining to consider overfill to be a discount for purposes of the ASP calculation — namely, operational feasibility.").

C. The 2011 Regulation Prohibiting Overfill Billing

No rule or regulation expressly prohibited billing for overfill until January 1, 2011. Then, effective January 1, 2011, CMS issued a regulation specifically and clearly addressing overfill. "No payment is made for amounts of product in excess of that reflected on the FDA-approved label." 42 C.F.R. 414.904(a)(3)(iii).

Although the rule was not effective until January 1, 2011, according to CMS, the prohibition against billing for overfill was not a new policy. This prohibition was instead a clarification of existing policy. CMS explained by first recognizing the "longstanding Medicare policy that in order to meet the general requirements for coverage under the 'incident to' provision, services or supplies should represent an expense incurred by the physician or entity billing for the services or supplies."[7] 75 Fed. Reg. 73170, 73468 (Nov. 29, 2010). As Defendant had previously argued, and the Court agreed, the "incident to" provision refers to § 1395x(s)(2)(A), which covers "services and supplies (including drugs and biologicals which are not usually self-administered by the patient) furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills (or would have been so included but for the application of section 1395w-3b of this title)." 42 U.S.C. § 1395x(s)(2)(A). ESRD

[7] The "incident to" provision applies to "services and supplies (including drugs and biologicals which are not usually self-administered by the patient) furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills (or would have been so included but for the application of section 1395w-3b of this title)." 42 U.S.C. § 1395x(s)(2)(A). The Court addresses Relator's argument regarding the incident to provision below in Part V.

drugs provided in dialysis clinics are not "furnished as an incident to a physician's professional service." (*See infra* Part V.) Nonetheless, CMS affirmed the general Medicare principle that it would not reimburse providers, including ESRD clinics, for medicine the providers received at no cost.

CMS then explained that, under the current ASP reimbursement methodology, CMS disregarded overfill and thus, so should providers when submitting bills to Medicare. *See* 75 Fed. Reg. at 73466-67. "Our ASP payment calculations are based on data reported to us by manufacturers," CMS explained. *Id.* at 73466. The Secretary chose not to include overfill as a "price concession," because, as mentioned above, it was operationally infeasible to do so. *See* 75 Fed. Reg. at 73461-73471. Thus, the data CMS used to calculate ASP excluded the financial impact of overfill. The Secretary calculates ASP based on the amount of product in the vial "as indicated on the FDA approved label," and as such, excludes overfill. *Id.* Because overfill is included in the ASP calculation, CMS did not recognize it as an incurred cost to providers. For this reason, CMS promulgated the 2011 rule "merely to clarify the Medicare ASP payment limit is based on the amount of drug conspicuously indicated on the FDA label, and that no payment will be made for any intentional overfill included as free drug for the proper preparation of a single therapeutic dose." *Id.* at 73467.

Under the new rules, however, ESRD clinics could opt in to a bundled fee reimbursement scheme under an ESRD composite rate. *See* 42 C.F.R. § 414.900(b) (listing examples of drugs subject to the ASP reimbursement

methodology). Fresenius opted in to this composite rate and thus, as of January 1, 2011, Fresenius was no longer reimbursed for Epogen or Zemplar based on the ASP.

D. First Cross-Motions for Summary Judgment: Falsity

Relator filed this qui tam action in 2010. Relator argues that the practice of billing Medicare for overfill from 2005 through 2006 violated the relevant Medicare rules and regulations prohibiting reimbursement for drugs providers receive for free.

Upon the parties' request, the Court bifurcated the summary judgment briefing schedule to first consider whether the submission of a request for payment for overfill administration satisfied the threshold falsity element of a False Claims Act claim, i.e. whether overfill administration was reimbursable under the Medicare rules and regulations existing at the time. The parties agreed that only if the Court answered this question in the affirmative would they engage in additional discovery on the remaining elements of a False Claims Act claim. Thus, whether Fresenius acted with the requisite level of scienter to be liable under the False Claims Act was not before the Court.

On September 17, 2013, the Court held, consistent with CMS's 2011 retrospective description of the Medicare landscape, that Fresenius was not permitted to bill Medicare for Epogen and Zemplar overfill from January 1, 2006 through December 31, 2010, the time when ASP methodology applied. *United States ex rel. Saldivar v. Fresenius Medical Care Holdings, Inc.*, 972 F. Supp. 2d

1339 (N.D. Ga. 2013). The Court recognized that, although the 2011 rule was not retroactive, according to CMS, the 2011 rule was a clarification of existing policy. The Court then took a deeper look at the existing rules and regulations and agreed that since the application of the ASP methodology excluded overfill, overfill administration was not reimbursable. The Court noted that no Medicare rule or regulation authorized reimbursement when the providers, whether ESRD clinics or physicians, incurred no expense. The Court relied on, *inter alia*, the assumption, implicit in Medicare reimbursement rules, that payments are generally made for "expenses incurred." *See* 42 U.S.C. § 1395y(a); 42 U.S.C. § 1395rr(b)(2)(B) (directing the Secretary to determine the reimbursement amount for ESRD separately billable, guided by the costs incurred by providers). (*See also* Alexander Dep. at 111 ("Carving out incident-to and wording about incident-to has no bearing on the fact that all entities in the Medicare system are, you know, prohibited from billing for things that are not an expense.").[8] Although the then-existing rules and regulations were ambiguous as to overfill billing, *see Saldivar*, 972 F. Supp. 2d at n.23, the Court held that a variety of Medicare principles, rules, and regulations, and in particular the changes to the reimbursement methodology that went into effect for Epogen and Zemplar in 2006, supported the conclusion that overfill administration was not reimbursable from 2006 through 2010. Because Relator had not sufficiently argued that

[8] Dr. James E. Alexander is Relator's expert witness.

overfill billing was impermissible before 2006, the Court did not address that possibility.

The Court's decision resolved only the first threshold element of an FCA claim: whether the request for reimbursement for overfill administration constituted a "false claim." As the Court explained, Fresenius would not be liable on an FCA claim, and not face treble damages, unless its submission of these "false claims" was done with knowledge of the falsity. *See Saldivar*, 972 F. Supp. 2d at 1358 ("[L]iability in this case may turn on whether CMS's policy prohibiting reimbursement of overfill was sufficiently clear prior to the issuance of its November 2010 rule, such that [Fresenius's conduct] if proved, must have been undertaken at least in reckless disregard of the policy." (quoting *United States ex rel. Westmoreland v. Amgen Inc.*, 812 F. Supp. 2d 39, 71 (D. Mass. 2011))). The Court did not consider, at that time, any evidence of Fresenius's knowledge or recklessness.[9]

The parties have now moved for summary judgment on the knowledge element of Relator's FCA claim. Specifically, the question before the Court is

[9] If the Court had been, at that time, presented with the record as it is now developed, the Court would likely not have reached the falsity element at all. Whether overfill administration was reimbursable from 2006 through 2010 is not clear on the face of any one statute or regulation. And although, as explained in this Order, there were those in the industry who believed overfill administration was not reimbursable during that time, given the ambiguity in the Medicare rules and the record now presented, no reasonable jury could decide that Fresenius was reckless, let alone acted with actual knowledge that overfill was not reimbursable. Thus, had the Court considered falsity and knowledge together, it would have likely declined to decide the falsity issue, holding only that Fresenius could not be held liable under the FCA because it did not act with the requisite knowledge. This does not mean, however, that government contractors capitalizing on ambiguity in rules, regulations or contracts won't face FCA liability where the contractors actually know that, despite the ambiguity, their actions were impermissible, or where the contractors were faced with credible, authoritative warnings and recklessly failed to heed them.

whether Fresenius submitted requests for reimbursement for overfill administration knowing, or recklessly disregarding, that overfill was not reimbursable under the Medicare rules and regulations.

Upon a thorough consideration of the factual record, which the Court describes next, and with the benefit of oral argument, the Court holds that no reasonable jury could find Fresenius acted knowingly or recklessly such that it could be held liable under the False Claims Act.

III. FACTUAL BACKGROUND

The record contains evidence suggesting that Fresenius's executives and attorneys believed at all relevant times that billing Medicare for overfill was permissible. Relator does not meaningfully disagree that the record contains such evidence. Instead, Relator argues that Fresenius's belief that billing for overfill was permissible was unreasonable. According to Relator, other evidence in the record proves that Fresenius's executives and attorneys knew that, after the implementation of the ASP methodology in 2006, and perhaps even before, billing for overfill was not allowed. Relator also suggests that evidence of Fresenius's disclosures to the government or knowledge of overfill permissibility before Medicare adopted the ASP methodology for Epogen and Zemplar is immaterial to the parties' cross-motions for summary judgment.

The Court first summarizes evidence of Fresenius's belief regarding overfill billing, based primarily on testimony of Fresenius's executives and attorneys.

The Court then details more thoroughly how Fresenius's executives and attorneys came to this belief, and evidence that arguably contradicts this belief.

A. Fresenius's Belief Regarding Overfill Billing

Fresenius's executives and attorneys unquestionably understood that reentry of Epogen and Zemplar vials and administration of overfill was consistent with (and in fact may have been required by) Medicare guidance to avoid drug wastage and to act as an efficient provider. Relator does not dispute this, expressly agreeing that utilization and administration of overfill "is and always has been legal." (Relator Resp. DSUMF ¶ 692.)

Fresenius executives and attorneys also believed that Medicare rules and regulations did not prohibit billing Medicare for the extracted overfill. Tracy Franklin is Fresenius's Director of Collections. From 2004 through 2010, she oversaw responsibility for Fresenius's Medicare billing to fiscal intermediaries including TrailBlazer Health Enterprises, LLC ("TrailBlazer"). (Def. Ex. 184 ("Franklin Decl.") ¶ 3.) Franklin authorized the submission of claims for Epogen and Zemplar without regard to whether some of the medicine constituted overfill, and during this time, she believed that such claims were in compliance with all applicable rules. (*Id.* ¶ 34.) She explained, "No statute, regulation or guidance instructed an independent dialysis facility to treat administered doses of overfill any differently than any other administered dose." (*Id.* ¶ 11.) And the claim form supplied by CMS did not request information about whether overfill was included in the units administered. (*Id.*) On the contrary, based on CMS guidance,

Franklin understood that Fresenius should bill for the amount of the drug that was administered to each patient, period. (*Id.*)

Likewise, Robert McGorty, Fresenius's Senior Vice President for Finance and Administration, believed that at all relevant times, the use and Medicare billing of overfill was permissible and consistent with industry practice. (*See* Def. Ex. 116 ("2013 McGorty Decl.") ¶ 23.) To be sure, much of McGorty's belief appears to be based on facts that predate the ASP methodology. Nonetheless, McGorty avers that Fresenius "openly and widely discussed" its use of overfill and overfill's impact on profits with CMS and the Medicare Payment Advisory Commission ("MedPAC") both prior to and during the years at issue in this case. (*Id.* ¶ 32.)[10] McGorty also testified that Fresenius never considered overfill "free." (*Id.* ¶¶ 14-16; *see also* Def. Ex. 176 ("Snail Report") at 29-34; Def. Ex. 177 ("Expert Report of Alan Bruce Steinwald") ¶¶9-10, 33-36.)

Fresenius at all times believed that, regardless of the amount Fresenius was reimbursed for the administration of ESRD drugs, Fresenius itself incurred an expense associated with the purchase of all the medicine in an ESRD vial, including overfill. (Def. Ex. 116 ("2013 McGorty Decl.") ¶¶ 14-16; *see also* Def. Ex. 217 at 2.) According to McGorty, "Fresenius has, in its own books and records

[10] Fresenius also relies on the declaration of John Markus. According to Markus, Fresenius understood that billing Medicare for overfill was permissible because he is aware of no statute, regulation or rule prohibiting this practice prior to January 1, 2011. (Def. Ex. 19 "Markus Decl.") ¶ 30.) But John Markus was Fresenius's Senior Vice President for Corporate Compliance only from May 1999 through January 2004. (Markus Decl. ¶ 1.) While Mr. Markus can speak to Fresenius's knowledge during his tenure there, he can not testify regarding Fresenius's knowledge after he left its employ.

always treated overfill as something that it pays for and that must be counted as part of the overall costs incurred by Fresenius." (2013 McGorty Decl. ¶ 16.)

Fresenius's lawyers also believed that overfill billing was permissible at all relevant times. For example, Fresenius's in-house counsel, Ronald L. Castle avers that at all relevant times, he believed billing for overfill was lawful and advised Fresenius as such. (Def. Ex. 51 ("2015 Castle Decl.") ¶ 6.) Castle has served as Fresenius's Deputy General Counsel for Litigation since July 1, 2005. He bases his opinion on a variety of factors including: (1) multiple disclosures to the government regarding the use and billing of overfill pursuant to numerous investigations from the 1990s through 2008 and the government's decision not to pursue claims based on this practice, and in particular not to pursue claims against Fresenius based on its extraction, utilization or billing of overfill; and (2) the lack of any statute or regulation specifically prohibiting billing for overfill. Another Fresenius in-house attorney, David Kembel,[11] stated that in 2006, in connection with reviewing Zemplar overfill capturing procedures and providing legal advice regarding such procedures, he "understood there was no prohibition on using and billing for Epogen and Zemplar overfill administered to patients and that CMS was aware that Fresenius was using and billing for Epogen and Zemplar overfill." (Def. Ex. 9 ("2015 Kembel Decl.") ¶¶ 37-39.) He further testified that, as far as he understood, "at all times prior to January 1, 2011, that

[11] David Kembel was the Associate General Counsel in the Legal Department at Fresenius during the relevant time periods. (Def. Ex. 9 ("2015 Kembel Decl.") ¶¶ 1-2.) He is now the Chief Compliance Officer. (*Id.*¶ 1.)

there was no regulation or statute that prohibited dialysis facilities from billing Medicare for Epogen or Zemplar overfill administered to patients in furnishing prescribed dosages of these separately billable drugs." (*Id.* ¶ 4.)

The record also contains instances in which Fresenius's attorneys advised Fresenius that overfill billing was permitted. Attorneys so advised in connection with several qui tam actions involving overfill predating the 2006 ASP Methodology's application to Epogen and Zemplar. These attorneys advised Fresenius that, at least at the time of those complaints, overfill utilization and billing was permissible. (*See* 2015 Castle Decl. ¶¶ 12-13, 20, 24, 46.) Likewise, in connection with Fresenius's merger with Renal Care Group, Fresenius's outside counsel Harvey Yampolsky stated in 2006 that overfill billing is appropriate if actually administered to the patient. (Def. Ex. 198 ("[T]he bottom line is that today it is still possible to bill for 'wastage' (although not for overfill unless it is actually utilized to fill a prescription).") And when, in 2005, Fresenius was presented with a document suggesting that a Medicare intermediary would not reimburse physicians for overfill administered in their offices, Fresenius's counsel advised the company that the policy did not seem to apply to ESRD facilities. Other examples are provided below, but it is fair to say that Fresenius's inside and outside counsel believed overfill billing was permissible throughout the relevant time period. Relator has identified no evidence to the contrary.[12]

[12] For what it's worth, the Court also notes that further down the corporate hierarchy, Fresenius employees and technicians openly understood that Fresenius was utilizing overfill and billing Medicare for the Epogen and Zemplar actually administered, whether or not the drug could be

While the record contains no evidence of Fresenius's specific knowledge that overfill billing was impermissible, Fresenius's executives and counsel were aware of certain facts that could have arguably led them to conclude that billing for free overfill was impermissible. For example, some evidence suggests that Fresenius knew its clinics could not bill for certain free drugs or services. (*See* Markus Dep. at 12-13 (testifying that while "it is permissible to bill for services in connection with a clinical trial" it was not permissible to do so if "any of the costs are furnished by the research funder").) And Fresenius appears to have understood that physicians billing under what those in the industry call the "incident to" provision, 42 U.S.C. § 1395x(s)(2)(A), had to incur an expense in order to bill Medicare for a drug. (2012 Kembel Dep. at 105; 2014 Kembel Dep. at 71.) Finally, viewed in the light most favorable to Relator, Fresenius understood that CMS did not account for overfill when setting the Epogen or Zemplar reimbursement rates from 2005 through 2010.

B. OIG Reviews and Investigations and CMS's Reimbursement Calculations

From the late 1990s through 2009, OIG has engaged in several reviews of ESRD reimbursement and investigations into Fresenius's billing practices. CMS also changed its methodology for setting reimbursement rates during this time.

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attributed to overfill. (*See* Relator Dep. at 48-49, 64-65.) Relator points out, however, that he was terminated when he raised concerns "about the fact that the drugs administered to patients did not meet the physical inventory of drugs available in the clinics." (Relator Resp. Def. SUMF ¶ 698.) Relator did not cite the Court to testimony that Relator complained of overfill billing practices, and in fact Relator admits that his complaints did not address billing or use of overfill involving Zemplar. (Relator Dep. at 73.) Fresenius also points out that no one with the company ever tried to keep Fresenius's use and billing of overfill a secret.

Fresenius was actively monitoring or participating in these reviews and changes, which provide some insight into whether Fresenius had the requisite intent necessary to support an FCA claim based on overfill billing.

1. 1997 OIG Review of Epogen Reimbursement

In 1997, OIG undertook a review of the price dialysis facilities paid for Epogen to determine if Medicare's reimbursement for Epogen should be reduced. The purpose of OIG's 1997 report was to provide cost information to CMS along with a recommendation regarding an appropriate reimbursement rate. At that time, the reimbursement rate for Epogen was $10 per 1,000 units administered.

The 1997 OIG report and accompanying drafts and work papers recognized the cost-savings potential for utilization of overfill, both to providers and to the government. (*See* Def. SUMF ¶¶ 134-161.) The report notes that its cost information consisted "of the amount providers paid to wholesalers for EPO as well as the actual amount of EPO administered during the year." (Def. Ex. 3 at 8.) Thus, the data in the 1997 report "would also contain the amount of any additional EPO that providers extracted from each vial." (*Id.*) After reviewing, among other things, applicable Medicare laws and regulations, cost reports from free-standing dialysis clinics, and current invoices and information regarding year-end rebates or free product, OIG recommended that CMS reduce the Medicare reimbursement amount to $9 per 1,000 units in order to capitalize on savings resulting from overfill utilization. (Def. Ex. 3 at 1, 8.) It is fair to say that in 1997, OIG understood that dialysis clinics were capturing, administering and

billing for overfill and that OIG did not view overfill as a separable "free product," but rather as a mechanism to reduce the acquisition cost.

CMS reviewed and commented on the 1997 report. (Def. Ex. 3 at 17-18.) It did not suggest in its comments that dialysis facilities should refrain from billing for administered overfill. (*Id.*)

2. The Medicare Modernization Act of 2003, the 2004 OIG Review of Medicare Reimbursement for ESRD Drugs, and the 2005 Average Acquisition Cost Rule

In 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"). The MMA contemplated that reimbursement for most ESRD drugs would be based on the average acquisition costs ("AAC") and ultimately average sales price ("ASP") rather than the average wholesale price ("AWP"). 42 U.S.C. § 1395rr(b)(13)(A)(iii). Congress delegated to the Secretary of Health and Human Services (the "Secretary") the task of calculating the ASP. The MMA also mandated that OIG again review acquisition cost to facilities for certain drugs, including Epogen and Zemplar. *See* MMA, Pub. L. 108-173, § 623(c). Thus, in 2004, OIG began such a review.

The purpose of the 2004 OIG study was twofold. (Def. Ex. 5 at 1.) First, the study endeavored "to determine the difference between the Medicare payment amount for separately billable end-stage renal disease drugs and the acquisition costs of these drugs for facilities." (*Id.*) Second, the study estimated the rate of growth of facilities' expenditures for these drugs. (*Id.*) The result of

this study was to form the basis for both the 2005 dialysis payment rate and the separately billable drug reimbursement rate.

At the outset, OIG met with CMS and industry representatives. Based on its initial meeting with CMS, OIG understood that CMS would use the results of the study "to promulgate a new rule, receive comments, and publish it before the end of 2004." (Def. Ex. 117.) Then in February 2004, OIG held two meetings with industry representatives. (Def. Ex. 119.) A Fresenius representative participated in these meetings. OIG informed participants that it would "most likely not include spoilage, waste, etc. [i]n [its] definition of acquisition cost" because it was "too difficult to get an accurate gauge of, and most likely varies between companies." (*Id.*) Companies were, however, encouraged to include such information in their reports to OIG and were also reminded that they could add information about additional cost factors during the comment period for the new rule. (*Id.*)

OIG later provided the companies with a request for information on the acquisition costs of the separately billable drugs and biologicals. (Def. Exs. 120-121.) In a March 1, 2004 letter, OIG requested information on Fresenius's drug acquisition costs in connection with the 2004 OIG study. (Def. Ex. 121.) The letter reiterated that the purpose of the study was to "determine the difference between the Medicare payment amount for separately billable end stage renal disease ('ESRD') drugs and the acquisition costs of these drugs for facilities." (*Id.* at 1.) The letter further explained that CMS would use data from this study "to

set calendar year 2005 reimbursement rates for all ESRD drugs, including EPO." (*Id.*)

Included in the March 2004 letter were instructions setting out OIG's definition of acquisition cost and the requested data. (*Id.* at 2.) Respondents were instructed to calculate average acquisition cost by dividing the total amount paid by all facilities owned or managed by the company for 2003 by the total number of units bought by the facilities owned or managed by the company in that year. Consistent with the provisions of the MMA regarding ASP, 42 U.S.C. § 1395w-3a(c)(3), the average acquisition costs was to be "net of volume discounts, prompt pay discounts, cash discounts, free goods contingent on any purchase requirement, chargebacks, and rebates (other than rebates under the Medicaid drug rebate program)." (*Id.*) Although the instructions did not mention overfill, they invited respondents to "provide separate information on other costs associated with the acquisition of drugs in the space provided on the worksheet." (*Id.*)

Fresenius's Senior Vice President for Finance and Administration, Robert McGorty emailed Kathleen Smith, another Fresenius executive, asking for guidance on how to handle overfill in Fresenius's acquisition cost reporting. (Relator Ex. 11.) Her initial response was to "ignore the overfill," but Smith said she would check with Fresenius's counsel, Ron Castle, who would address this issue with David Tawes, OIG's project leader for the 2004 audit. (*Id.*) The next day, Smith responded that "Ron had heard back from Dave Tawes" who

instructed Fresenius to footnote achievable utilization of overfill for those drugs for which it captured overfill. (Def. Ex. 122.)

Fresenius then responded to OIG's request for information by letter to Mr. Tawes dated March 12, 2004. (Def. Ex. 123.) In its letter, Fresenius expressly stated that its use of overfill should be considered when analyzing acquisition cost for Epogen and Zemplar. (*Id.*)

> FMCNA's profit margin on EPO administration is partly derived from overfill utilization. ***Any analysis that attempts to quantify margin on EPO should consider this.*** For the full year 2003, FMC achieved a 13.8 overfill utilization percentage. For Q4 of 2003, the overfill utilization was down to 13.2%. It should be noted that in 2003, Amgen reduced the targeted overfill amount by 3% and could reduce overfill even further in the future. It is not clear if FMCNA has seen the full impact of the 3% decline in our Q4 number.
>
> The company also utilizes overfill for Zemplar. This practice began in January 2003. The company's Zemplar overfill experience for 2003 was 12.9%.

(*Id.* (emphasis added); *see also* Def. Ex. 124 (revised letter to OIG reiterating the statements regarding overfill usage).)

Fresenius was not the only large dialysis company to report its utilization of overfill to OIG. Both Renal Care Group ("RCG") and DaVita reported the use of overfill to offset Epogen acquisition costs. (Def. Exs. 125, 126.) That three of the largest dialysis companies reported overfill percentages to OIG was memorialized by OIG in the work papers associated with the 2004 OIG audit. A fourth large dialysis center, Gambro, did not include overfill information in its report to OIG.

Neither the reports by the companies, nor the OIG work papers, suggested that the companies utilized overfill but only billed private payors, as opposed to Medicare. Mr. Tawes testified that he understood from these disclosures that Fresenius, RCG and DaVita were all using and billing Medicare for overfill. (Tawes Dep. at 79-81, 99, Def. Ex. 38.) Mr. Tawes notes, however, that OIG did not request or receive any information from Fresenius regarding overfill practices after 2004, and Tawes had no knowledge as to whether Fresenius continued to bill Medicare for overfill after 2004. (*See* Tawes Dep. at 114-115.)

Although OIG was aware that dialysis facilities included overfill in their own determination of profit margins, the 2004 OIG report to CMS did not account for overfill in any of the acquisition cost calculations. OIG explained that the amount of overfill varies and facilities have different practices regarding the utilization of overfill. (Def. Ex. 5 at 8-9.)[13] Viewed in the light most favorable to Relator, the record suggests that Fresenius knew OIG's calculations did not consider overfill. (Relator Ex. 22; *see also* Relator Ex. 23)

[13] Relator asserts that the 2004 OIG Report proves that it "was widely understood in the Medicare community that ESRD drugs other than Epogen were covered under Part B "incident to" rules because they fit the definition of drugs that were generally not self-administered." (Relator SUMF ¶ 12, Doc. 217-2.) This is not so. The 2004 Report simply recognizes that, other than Epogen, ESRD drugs are not self-administered. (Def. Ex. 5 at 1 ("Medicare coverage of separately billable drugs in dialysis facilities is limited to products that cannot be self-administered, i.e., drugs that are administered by a health care professional. The exception to this requirement is EPO . . . . EPO furnished by dialysis facilities is covered even if it is self-administered by the patient.").) As the Court explains in Part V, to be covered by the incident to provision of 42 U.S.C. § 1395x(s)(2)(A), the drugs "which are not usually self-administered by the patient" must be "furnished as incident to a physician's professional service" and generally be "of kinds which are commonly furnished in physician's offices."

CMS reviewed the 2004 OIG report and provided its written response on April 15, 2004, indicating that it had read and considered the report. (*Id.* at 14-15.) CMS's proposed rule setting reimbursement amounts, 69 Fed. Reg. 47488 (Aug. 5, 2004), did not consider overfill amounts in determining acquisition costs for Epogen. (*See* Relator Ex. 23.) Nonetheless, according to John Warren, CMS's Rule 30(b)(6) designee, CMS did "take . . . into account" the information regarding overfill supplied by OIG when setting the reimbursement rate for ESRD drugs. (*See* 2014 Warren Dep. at 116.) In other words, according to Warren, CMS considered the fact that dialysis centers were using overfill to lower acquisition costs when it set reimbursement rates for Epogen. (*Id.* at 64, 116-117.)

Fresenius objected to CMS's proposed rule. (Relator Ex. 23.) Fresenius's CEO explained to CMS that "providers generally utilize the overfill amount to minimize cost and wastage." (*Id.* at 4.) He disclosed that this was "a widely and accepted practice in the dialysis industry." (*Id.*) And he encouraged CMS to factor overfill utilization into its acquisition cost estimates.

> CMS should include, as a factor for overfill utilization, a 10 percent reduction in acquisition costs and should include a similar factor reflecting changes in overfill as a component of future acquisition cost updates. *Failure to recognize the impact of overfill utilization on acquisition cost will result in an initially overstated acquisition cost and hidden cost increases as manufacturers continue to reduce overfill amounts, which has been the history with EPO.*

(*Id.* (emphasis added).)

CMS was apparently not persuaded by Fresenius's objection. Its final rules setting reimbursement calculation for average acquisition cost (which would be used for Epogen and Zemplar reimbursements in 2005) and average sales price (which would be used for Epogen and Zemplar from 2006 through 2010) did not take overfill into account. As Relator notes, had CMS included overfill in its reimbursement calculations, the reimbursement amount would have been lower (and thus dialysis facilities would have received less per dose). (*See also* Tawes Dep. at 87-88 (testifying that CMS's reimbursement amount was higher because it did not factor overfill into the reimbursement calculation).)

3. The ASP Methodology and its Disregard for Overfill

By 2006, Medicare was using the ASP methodology for ESRD drugs. Although the Secretary was authorized to consider overfill as a price concession in determining the ASP for reimbursement purposes, the Secretary did not do so. And, with one exception, the record suggests that Fresenius understood, or should have understood, that overfill was not factored into the ASP determination or OIG's acquisition cost reports in 2006, 2008 and 2010.[14]

For example, in October 2005, Fresenius executives considered a memorandum that "thorough[ly] review[ed]" the ASP methodology. (Relator Ex. 27.) The memorandum indicates that manufacturers report ASP to CMS. According to the memorandum, manufacturers calculate ASP by dividing the

[14] Relator also relies on exhibits 24, 25, and 26 to support his assertion that Fresenius knew that overfill was excluded from ASP calculations used by CMS to reimburse ESRD drugs from 2006 forward. These exhibits do not support this assertion, showing only that Fresenius was aware of the ASP methodology.

"total U.S. sales for a National Drug Code ('NDC') by the total number of units sold (a unit is defined as the lowest identifiable quantity of the drug or biological by NDC that is dispensed, exclusive of diluents)." (Relator Ex. 27 at 1-2.) The memorandum tracks the language of the statute and regulation, noting that the ASP must include several price concessions including discounts and free goods contingent on any purchase requirement. (*Id.* at 2.) The memorandum does not mention overfill, suggesting that overfill was not factored into the ASP calculations.

Communications in connection with the 2010 OIG acquisition cost report likewise suggest Fresenius understood overfill was not factored into acquisition cost. In 2009, in response to a request from a congressperson, OIG sent Fresenius another request for information about its acquisition costs for separately billable ESRD drugs. (Def. Ex. 178.) Similar to the 2004 OIG request, the 2009 request asked independent dialysis facilities to report the total amount paid by the facility for a product for the first quarter of 2009 divided by the total number of units bought by the facility for that quarter. Again, facilities were instructed that the average acquisition cost "should be net of volume discounts, prompt pay discounts, cash discounts, free goods contingent on any purchase requirement, chargebacks, and rebates (other than rebates under the Medicaid drug rebate program)." (Def. Ex. 178 at 4.) Unlike the 2004 request, however, this time OIG did not invite respondents to provide separate information on other costs. Accordingly, this time, dialysis facilities did not include overfill

information in their report to OIG. Nonetheless, at no point during the OIG cost report study in 2004, or in subsequent studies in 2006, 2008 or 2010, did Mr. Tawes become aware of any rule or regulation that would prohibit using or billing overfill, nor was he aware of anything that would put a provider on notice that such a rule existed. (Tawes Dep. 106-109.)[15]

In October 2008, Fresenius became licensed to sell Venofer, a different ESRD drug subject to ASP reimbursement requirements. (Relator Ex. 28 at 9.)[16] Fresenius thus began reporting Venofer ASP to CMS, and in doing so, reported the price for a package of vials, along with the volume per vials and vials per National Drug Code. (*Id.* at 3.) It does not appear that the ASP for Venofer accounted for overfill.[17]

Fresenius's internal ASP compliance policy, adopted in 2008, recognizes that ASP is "performed at the package level, characterized by an 11-digit NDC number (the 'NDC-11') and representing a single package size." (Relator Ex. 29 at 15.) The policy continues, "Therefore, an ASP value is calculated and reported for each package size." (*Id.*) Thus, based on this evidence, a jury could easily infer

[15] It is not clear from the record the parties cite whether Tawes would have had any reason to inquire into the permissibility of billing for overfill administration. (*See* Tawes Dep. at 106 (noting that OIG made no determination regarding the permissibility of overfill billing in its reports to CMS).)

[16] Page 9 of Relator's exhibit 28 is page 5 of the 2009 letter contained in that exhibit.

[17] Fresenius asserts that by the time it began reporting Venofer ASP, Venofer, like Zemplar, was available only in single-use vials and reentry into those vials was prohibited. (Def. Resp. Relator SUMF ¶ 26, Doc. 233.) Fresenius seems to suggest, therefore, that the reporting of Venofer ASP would not shed light on Fresenius's understanding of ASP. The Court disagrees. As Fresenius itself explains, "[d]uring the time period at issue, there was no relevant difference in the Medicare reimbursement rules for Epogen® and Zemplar®." (Def. Resp. Relator SUMF ¶ 67, Doc. 233.) In other words, for reimbursement purposes, Fresenius's knowledge of ASP reporting requirements for one ESRD drug (e.g., Venofer) is relevant to its knowledge of such requirements for any other ESRD drug (e.g., Epogen or Zemplar).

that Fresenius understood ASP was based on the amount of drug in a single package, as labeled on the package, exclusive of overfill.

Despite the evidence above, Ron Castle, Fresenius's in-house counsel, testified in 2012 that he believed Medicare factored in overfill in setting its reimbursement amount. (2012 Castle Dep. at 84-86.) He explained that Fresenius's "costs are not in any direct way part of our charge or allowable payment from Medicare." (*Id.* at 85.) In other words, reimbursement for Epogen and Zemplar is based on a value CMS calculates, but not on the actual cost to any one provider. And in Castle's view, providers reported their use of overfill to CMS, and CMS knew providers utilized overfill, during the relevant time periods. (*Id.*) Thus, although overfill was not "accounted for" in the acquisition cost calculations, Castle still apparently believed CMS factored it in when setting the ASP reimbursement rate. (*Id.*)

4. Other OIG Investigations

OIG also investigated and reported on payments made for Epogen administered at seven Fresenius dialysis facilities. Between October 2007 and April 2009, Fresenius provided a series of documents related to Epogen billing practices. (Def. Exs. 91, 152-153.) These included a copy of the Fresenius 2006 Annual Report it had previously provided to OIG in connection with a Corporate Integrity Agreement.[18] (*See* Def. Ex. 153 (noting that the "FMCNA 2006 OIG

[18] The Corporate Integrity Agreement ("CIA") between OIG and Fresenius arose out of a settlement regarding conduct of National Medical Care ("NMC"), a company Fresenius acquired

Annual Report" was produced to OIG in 2009); *see* Part III.E.2 below).) Somewhat buried in this Annual Report is a document referencing Fresenius's practice of utilizing the "maximum amount of overfill [f]or the billing of Epogen to the payor." (Def. Ex. 152, Doc. 221-36 at 121.) This document does not indicate the date when Fresenius was billing Epogen overfill to the payor. In June 2008, Fresenius also supplied OIG with a copy of its Epogen administration policies dated October 14, 2002 and May 12, 2004. (Def. Ex. 153.) These policies directed clinics to reenter vials in order to capture "residual" Epogen and achieve "maximum withdrawal of vial contents." (Def. Ex. 23 at 2-3, 5.) The policies do not address billing for overfill. And although Fresenius states that these policies were still in effect when they were provided to OIG in 2008, Fresenius does not direct the Court to evidence to support this or evidence suggesting that OIG understood the 2004 policies were still in effect in 2008.

C. CMS Cost Reports

In addition to the OIG reports discussed above, dialysis companies like Fresenius submit cost reports to CMS. (Def. Ex. 116 ("2013 McGorty Decl.") ¶¶ 4-6.) As part of the cost reports, dialysis facilities are instructed to include the total dollar amount spent on purchasing separately billable drugs such as Epogen and Zemplar, taking into account rebates and discounts. (*Id.* ¶ 8.) Fresenius's cost reports during the relevant time period include the total amounts spent on all separately billed drugs. (*Id.*) And for Epogen, the cost reports also include the

in 1996. (*See* Part III.E.2.) One purpose of the CIA was to ensure compliance with Medicare rules and regulations.

total number of units administered. (*Id.*; *see also* 2013 McGorty Decl. Ex. 1 at 4, 14.) Thus, according to Robert McGorty, Fresenius's Senior Vice President for Finance and Administration, anyone reviewing the cost reports could determine the actual per-unit cost of Epogen independent of the number of "labeled" units in a vial. (2013 McGorty Decl. ¶ 9.) For this reason, McGorty understood that Medicare considers the impact of overfill on Fresenius's costs when "considering the economics of dialysis reimbursement." (*Id.* ¶ 12.) And CMS's corporate designee, John Warren, agreed that the cost reports reflected the impact of overfill on reducing costs. Nonetheless, as noted previously, CMS did not factor overfill into its calculation of average acquisition cost or average sales price.

D. CDC and CMS Changes to the Reentry Protocol

The reentry protocols issued by the Centers for Disease Control and Prevention ("CDC") and CMS are relevant to Fresenius's understanding of overfill billing requirements. In the early 2000s, the CDC revised its recommendations regarding reentry into single-use vials, providing strict procedures to ensure patient safety and reduce the risk of infection. In response, Fresenius's Chief Medical Officer, Dr. J. Michael Lazarus, consulted with Fresenius's law department and issued a memorandum to the field instructing technicians to follow Fresenius policy and procedures when reentering single-use vials. (Def. Ex. 193.) In the letter, Dr. Lazarus stated that he had "been advised by [Fresenius's] Law Department that there is no regulation or ruling from any federal agency that restricts or prohibits use of overfill if carried out in [a]

clinically appropriate manner." (*Id.*) To be sure, the letter focused on CDC, not CMS guidelines, and does not expressly address whether it is appropriate to bill Medicare for administered overfill. This letter also predates the application of the ASP methodology to Epogen and Zemplar.

In January 2003, John Markus, Fresenius's then Vice President for Corporate Compliance, participated in an "Open Door Forum" with CMS. (Def. Ex. 19 ("Markus Decl.") ¶ 19.) At the Forum, CMS notified dialysis facilities that they could, and in fact were encouraged to, reenter vials where appropriate in order to reduce waste. (*Id.*; *see also* Warren 2014 Dep. at 96.) According to Markus, "[i]t was clearly understood by all knowledgeable participants in the Forum that the purpose of this guidance was to standardize industry practices relating to the capture and administration of overfill as part of the reentry process." (*Id.*)

Shortly thereafter, in February 2003, CMS directed dialysis facilities to comply with the CDC procedures and, "in general . . . bill what they administer to the patient." (Def. Ex. 17 at 6; Def. Ex. 18.) Fiscal intermediaries likewise encouraged "efficient utilization" of medications including reentry where allowed to avoid waste. (*See* Def. Ex. 21 at 2.) Although providers could bill Medicare for wastage under some circumstances, intermediaries discouraged doing so. (*Id.*; Def. Ex. 22 at 2.) Fresenius does not direct the Court to any evidence that fiscal intermediaries or CMS directed dialysis facilities to bill Medicare for overfill or expressly condoned the practice.

Effective October 14, 2008, CMS adopted regulations which referred to a new CDC rule prohibiting re-entry into single-use intravenous medication vials. (Def. Ex. 25.) *See* 42 C.F.R. § 494.30(a)(1)(i). The rule did not require immediate compliance. Fresenius, however, immediately set forth company-wide plans for implementing the new policy prohibiting re-entry into single use vials of Epogen and Zemplar. (Def. Ex. 28.) Fresenius continued to allow for re-entry of multi-use vials. (*Id.*) Because Zemplar was only available in single-use vials, Fresenius discontinued its practice of reentering Zemplar vials entirely.

E. Investigations and Other Qui Tam Actions

1. Ecksel and Zwick

In the early 1990s, representatives of the National Kidney Patients Foundation ("NKPF") notified the Department of Health and Human Services ("DHHS") that they were preparing a qui tam lawsuit against National Medical Care ("NMC"), a predecessor-in-interest to Fresenius Medical Care Holdings, Inc. The main thrust of their complaint was that dialysis facilities were dangerously reentering single-use vials of erythropoietin (Epogen or "EPO"), salvaging overfill to use for other patients. They filed their qui tam lawsuit in the United States District Court for the District of Columbia in December 1991, *United States ex rel. Ecksel and Rosen v. Amgen, Inc., et al.*, No. 91-3325 (D.D.C. 1991). The relators alleged that NMC and Amgen, the manufacturer of EPO, violated the False Claims Act, by "entering into secret arrangements" whereby Amgen would overfill vials and providers like NMC would then capitalize on this overfill,

providing the EPO at no extra cost. (Def. Ex. 46 ¶ 13.) "Thus the providers' actual cost is lower than that disclosed to the United States." (*Id.*)

Six months after the NKPF qui tam complaint was unsealed, the relators voluntarily dismissed the action. The United States did not object to dismissal.

One month later, the United States House of Representatives, Committee on Ways and Means, Subcommittee on Health held a hearing on "Payment Under Part A of the Medicare Program and Payment for Hospital Outpatient and End-Stage Renal Disease Services." (Def. Ex. 50.) Representatives of NKPF testified at the hearing, explaining how Amgen overfills EPO vials and "show[s] providers how they can bill the government for the excess in the vial." (*Id.* at 136.) The NKPF representatives explained that EPO was "free" to the providers. And according to the NKPF representatives, simply reducing the reimbursement rate would not solve the problem. Instead, the representatives urged Congress to eliminate overfill, which they characterized as a "kickback." (*Id.*)

NMC's troubles did not end there. In February 1996, an Amgen salesperson, Eric Zwick, filed another qui tam complaint. (Def. Ex. 52.) *United States ex rel. Zwick v. Amgen, Inc. et al.*, No. 96-1169 (E.D. Pa. Feb. 15, 1996). Zwick alleged that Amgen "intentionally 'overfilled' its Epogen vials by up to 25 percent and provided the overfill quantity to customers at no extra charge." (*Id.* ¶ 43.) Zwick further alleged that providers like NMC "bill[ed] Medicare for Epogen that they had received as free overfill." (*Id.* 45.) According to Zwick, Medicare regulations for EPO only allowed reimbursement "for use within the

scope of FDA labeling," and because the overfill was not part of the FDA label, providers "were not entitled to Medicare reimbursement for such use." (*Id.* ¶¶ 47-48.) Zwick alleged that the practice of extracting and billing for overfill violated the False Claims Act.

While the *Zwick* case was pending, Fresenius acquired NMC in September 1996. Thus, Fresenius succeeded to the responsibility and liability for the qui tam complaint.

The *Zwick* complaint was partially unsealed on November 5, 1996. In January 1997, Fresenius's outside counsel, Arent Fox, explained to the United States Department of Justice ("DOJ") why using and billing for overfill was consistent with Medicare rules and regulations. The Government did not intervene, and shortly after the complaint was fully unsealed, Zwick voluntarily dismissed the case. Fresenius's counsel, Ronald Castle, averred that "[b]ased on the investigation and the government's response to the discussions and presentation regarding the *Zwick* allegations, I and other Arent Fox attorneys concluded that the government did not dispute Fresenius's interpretation of the rules as related to overfill." (Def. Ex. 51 ("2015 Castle Decl.") ¶¶ 15-16.) Castle stated that Fresenius's lawyers never advised Fresenius to alter its overfill practices in any way. (*Id.*)

2. NMC and the Corporate Integrity Agreement (CIA), 2000 - 2008

Investigations into NMC's pre-merger conduct continued after the *Zwick* complaint was dismissed until Fresenius settled these investigations in 2000. As

part of the settlement, on January 18, 2000, Fresenius entered into a Corporate Integrity Agreement ("CIA") with OIG that lasted from 2000 through 2008. The CIA was "designed to 'ensure compliance' by Fresenius and its subsidiaries, employees, contractors, and agents, 'with the requirements of Medicare, Medicaid and all other Federal health care programs." (Def. Ex. 70 at 1-2.) The OIG Associate Counsel assigned to monitor Fresenius's compliance with the CIA was Nicole Caucci (formerly Nicole Hall).

Communications between Fresenius and Caucci, and Caucci's deposition testimony, show that Fresenius did not hide its overfill billing practices. For example, in an October 5, 2001 letter, Fresenius stated, "[i]nsofar as Epogen is billed to the Medicare program on the basis of units actually administered, the utilization of overfill amounts has no effect on facility reimbursement." (Def. Ex. 71 at 4.)

Likewise, in a November 4, 2002 letter, Fresenius notified Ms. Caucci that it had "noted an increase in the reported amount of overfill recovered from Epogen vials by [its] dialysis clinics." (Def. Ex. 92 at 1.) In particular, some clinics were reporting an average overfill of more than 16.8% — the target on average overfill contained in Epogen vials. "By itself," Fresenius explained, "an improvement in the Company's average rate of overfill recovery would not raise regulatory concerns." (*Id.*) Fresenius acknowledged, however, that "improvements in overfill recovery" should not be "achieved at the expense of dosing accuracy." (*Id.*) Fresenius endeavored to determine the basis for

increased overfill recovery and, in the meantime, voluntarily established an escrow account into which it would place a monthly estimate of revenue received from all payors that could be attributed to Epogen overfill in excess of 16.8%. (*Id.*) Ms. Caucci testified that she understood from this letter, and the fact that Fresenius set up an escrow account devoted to funds associated with overfill billing, that Fresenius was billing Medicare and other payors for Epogen overfill. (Caucci Dep. at 69.)

Fresenius sent Ms. Caucci a follow-up letter in February 2003. The letter explained that Fresenius had not yet completed its analyses or reached any final conclusions regarding the reported overfill discrepancy. However, Fresenius notified Caucci that it established the escrow account for estimated revenue attributable to Epogen overfill in excess of 16.8% and was in the process of developing a procedure for monitoring the accuracy of overfill utilization using scientific scales. (Def. Ex. 97.)

The next letter to Caucci, dated March 3, 2003, further confirmed Fresenius's utilization and billing for overfill. Fresenius's Senior Vice President John Markus explained the new Epogen monitoring program Fresenius had instituted and enclosed material describing this program. (Def. Ex. 98.) A critical aspect of the new program involved reducing the amount Fresenius billed Medicare for Epogen overfill amounts if the reported overfill amount exceeded 17%, which was below the 17.6 percent average overfill recently reported by Amgen. Markus explained, "Should the reported overfill exceed the maximum

amount calculated from the measured sample, all billing for Epogen amounts from that facility for that day will be reduced on a pro rata basis prior to billing." (*Id.*) Caucci assumed, based on this disclosure, that Fresenius would continue this program throughout the life of the CIA (through 2008) unless Fresenius notified her to the contrary. (Caucci Dep. at 79-80.) She did not recall Fresenius ever notifying her that it was discontinuing the program. (*Id.* at 79.)

In April 2003, Markus notified Caucci that Fresenius was discontinuing deposits into the escrow account, apparently because its use of scientific scales in clinics reporting consistently high levels of overfill recovery had been successful. (Def. Ex. 102.) Ms. Caucci shared the letters above with David Duff of the Office of Audit Services at OIG.

A separate March 2003 letter to Ms. Caucci addressed billing Medicare for Zemplar overfill. (Def. Ex. 99.) Here, David Kembel, Fresenius's Assistant General Counsel, explained that there was a "potential overpayment involving billings for Zemplar." (*Id.*) "In June, 2002," Kembel explained, "we became aware that a small number of FMCNA facilities were utilizing the overfill contained in vials of Zemplar. Upon further review, we determined that in some instances, this use of overfill could result in billing errors to Federal health care programs." (*Id.*)

> Specifically, in instances where the physician ordered between 5 and 6 mcg. of Zemplar the clinic staff could at times obtain the full dose from a single 5 mcg. vial. Our billing system was at the time programmed to bill for Zemplar in 5 mcg. increments based on the Medicare HCPCS code available at the time. Therefore, if the

> clinician were able to obtain the full dose from one vial of Zemplar, the billing system would still bill the administration as 10 mcg. even though only one vial was used. The same issue arises if the physician ordered between 10 and 11 mcg., *since Zemplar is sold in 10 mcg vials as well and the overfill could have been used to complete the prescribed dose.* A June 25, 2002 memorandum directed the facilities to discontinue utilizing Zemplar overfill until billing software changes could be made.

(*Id.* (emphasis added) (footnote omitted).) In other words, Fresenius disclosed to OIG (through Caucci) that its clinics were utilizing and billing Medicare for Zemplar overfill, but at times, inadvertently billing for more than was actually administered.

Kembel concluded by noting that a "late 2002 release of HCPCS code for Zemplar in 1 mcg. increments," allowed Fresenius to bill in these smaller increments, thus "tak[ing] into account the actual dose used in the administration of Zemplar." (*Id.* at 2.) "As a result of these changes," Kembel explained, "we are currently able to utilize Zemplar overfill and bill the actual dose administered." (*Id.*) According to Caucci, this letter confirmed that Fresenius had disclosed that it was both using Zemplar overfill and billing the government for it. (Caucci Dep. at 87.) And just as with Fresenius's policy regarding Epogen overfill, Caucci understood that Fresenius's Zemplar overfill policy would continue throughout the life of the CIA unless she was notified to the contrary. (*Id.* at 89.)

Caucci continued to communicate with Fresenius and David Duff of the Office of Audit Services at OIG regarding Zemplar and Epogen overfill billing in

2003. In these communications, Caucci indicated that she understood "that the potential overpayments are a result of [Fresenius] dialysis facilities utilizing overfill contained in vials of Zemplar." (Def. Ex. 105 at 1.) She received additional information from Fresenius regarding Epogen and Zemplar overfill billing. For example, in December 2003, Caucci received a letter from Fresenius's counsel, David Kembel, responding to her request for an example showing that CMS was aware that dialysis facilities use Epogen overfill. (Relator Ex. 46.) Fresenius provided a 1993 OIG audit of Epogen, which according to Fresenius "assumes that a facility multi-withdraws from a single vial of EPO to treat more than one patient." (*Id.* at 1.) Kembel further explained that "OIG used this cost data, including the assumption that the facility uses overfill, in making its reimbursement recommendations." (*Id.*)

Caucci also advised Duff that "Fresenius seem[ed] to be taking the issue of overfill recovery pretty seriously" and invited Duff to take a closer look at the Epogen overfill issues. (Def. Ex. 106 at 1.) She confirmed that Fresenius had offered to come in and explain its overfill practices. Duff declined to engage, stating, "At this time we are not going to get involved in the EPO overfill issue." (Def. Ex. 107.)

In September 2003, Caucci discussed Epogen overfill issues with Brady Augustine, Senior Advisor to the CMS Administrator. Among other things, Caucci reiterated how "seriously" Fresenius appeared to be taking the overfill issue, and asked if anyone at CMS could review the information and give a

reaction. (Def. Ex. 109.) Augustine agreed that Fresenius had been a "good corporate partner and has imposed quite restrictive policies on itself." (*Id.*) He noted in an email that CMS was "concerned about EPO use and overfill because it makes Program Integrity more difficul[t] and because there is so much potential for abuse." (*Id.*) Augustine has since testified that the "Program Integrity" issue he referred to in this email "was not whether billing for administered overfill was permitted or legal — [he] understood that it was." (Def. Ex. 36 at 24-25.) Instead, Mr. Augustine was concerned about whether overfill was accurately captured. The main issue was whether CMS "paid only for what was actually administered." (*Id.*) Augustine maintains that neither OIG nor CMS believed billing for overfill was prohibited in 2003.

Fresenius and Caucci continued to have open dialogue regarding Zemplar and Epogen overfill in 2004. And as before, Caucci continued to understand that Fresenius was utilizing and billing Medicare for overfill of Zemplar and Epogen.

In August 2006, Fresenius submitted a report to Caucci as required under the CIA. (Def. Ex. 150.) Other than noting that Fresenius was in the process of conducting Part 2 of the Zemplar overfill audit, the report does not address Zemplar or Epogen overfill.

Fresenius supplied to Caucci another annual report in March 2007. (Def. Ex. 152.)[19] This report included a copy of its Confidential Disclosure Log for 2006, logging concerns documented within the Company. In response to a

[19] This is the same report Fresenius provided to OIG during the 2007 through 2009 investigation into Epogen billing in seven Fresenius facilities. (*See infra* Part III.B.4.)

concern involving a "decrease in use of Epogen," the log confirms that Fresenius does in fact bill the use of Epogen "to the payor."

> Substantiated. Amgen publishes the overfill amount for each vial and FMCNA policy requires this overfill be tracked. Not all staff were following procedures at this facility when drawing up the medication in order to get maximum amount of overfill or the billing of Epogen to the payor. This was not effecting the patients['] care. Nurses have been assessed to ensure they are following FMCNA procedures.

(*Id.*) The log does not provide a date associated with this practice.

In sum, during the course of the CIA, from 2000 through 2008, Caucci found Fresenius "forthcoming" under the CIA and that it "fully disclosed" it was utilizing and billing Medicare for overfill. (Caucci Dep. at 99, 119, 147.) She disclosed Fresenius's overfill practices to others at OIG and to CMS. Neither Caucci nor anyone at OIG or CMS ever notified Fresenius that it was in violation of any CIA requirements based on overfill billing or CMS prohibition against such practice.

3. Hamel

In December 1999, John Hamel, a former Fresenius billing clerk, filed a qui tam complaint against Fresenius alleging fraudulent overfill billing. (Def. Ex. 62A.) *See United States ex rel. John Hamel v. Fresenius Medical Care North America*, No. 99 cv 12455 REK (D. Mass. Dec. 1, 1999). According to Hamel, Fresenius improperly billed Medicare for Epogen that it had received for free as part of a trial study and improperly billed for the administration of "residue Epogen it reused from prior treatments." (Def. Ex. 62A ¶¶ 29, 33.) As part of the *Hamel* investigation, Fresenius's outside counsel at Arent Fox, including Ron

Castle, prepared a presentation regarding Fresenius's overfill practices. The presentation detailed the history of Epogen overfill usage. At least by 2002, the Government had dropped claims related to overfill usage. (*See* Def. Ex. 66.)

4. Gambro

The Department of Justice investigated one of Fresenius's competitors, Gambro Healthcare, Inc. ("Gambro") in relation to a qui tam complaint filed against it. In response, in June 2002, Gambro submitted a white paper to the DOJ. (Def. Ex. 82.) The white paper was up-front about Gambro's utilization and billing Medicare for overfill. (*Id.* at 1, 6-8, 15-16.) For example, Gambro stated, "There is no prohibition on capturing and billing for all of the EPO contained in a vial, including overfill." (*Id.* at 1; *accord id.* at 7-8.) Gambro continued, "The government's principal concern in connection with EPO overfill appears to be whether Gambro bills Medicare for more units of EPO then actually are administered to patients." (*Id.* at 6.) Sometime around late 2004, the DOJ dropped all allegations against Gambro. (*See* Def. Ex. 84.) Fresenius's counsel knew sometime before March 2006 that Gambro had made a presentation regarding overfill to the government.

5. Renal Care Group

In 2005 and 2006, the U.S. Attorney's Office for the Eastern District of Missouri investigated Renal Care Group's and Fresenius's utilization of EPO and billing for overfill. During the course of the investigation, on March 31, 2006, Fresenius acquired Renal Care Group ("RCG"). In September 2006, a Fresenius

employee, Dr. Raymond Hakim, was interviewed by the FBI, OIG and DOJ. In the interview, Hakim discussed RCG's use of and billing for overfill, including the practice that was in place during 2006. According to Castle, who was present at the interview, "[n]one of the government representatives at the interview suggested that it was improper to bill for overfill actually administered." (Def. Ex. 51 ("2015 Castle Decl.") ¶ 35.) In 2007, in connection with this investigation, Fresenius filed a motion to quash a subpoena. Briefing in connection with this motion by both DOJ and Fresenius also discussed overfill. Following this investigation, neither the DOJ nor the U.S. Attorney's Office for the Eastern District of Missouri pursued any claims against Fresenius or RCG related to billing for prescribed dosages of Epogen overfill administered to patients. Based on this investigation, Fresenius's attorney, Castle, deduced that it was appropriate to bill for administered overfill. (*Id.* ¶¶ 35-36.)

6. Woodard

On November 25, 2002, former Amgen sales representatives Ivey Woodard filed an amended qui tam complaint in federal court in the Eastern District of Texas against Fresenius and others. *United States ex rel. Woodard v. Amgen, Inc., et al.*, No. 1:02-cv-0252-MAC (E.D. Tex. Nov. 25, 2002). Woodard alleged, *inter alia*, that Fresenius violated the FCA by billing Medicare for overfill, though no count was based specifically on such billing. (Def. Ex. 154 ¶¶ 48-49.) Woodard filed a second amended complaint on March 5, 2005 that contained the

same allegation. (Def. Ex. 146.) *United States ex rel. Woodard v. Fresenius Medicare Care, et al.*, No. 1:05-cv-0227-MAC-ZJH (E.D. Tex. Mar. 5, 2005).

In August 2007, in connection with the Government's investigation into Woodard's allegations, Fresenius was served with two subpoenas from OIG. (Def. Ex. 147.) The subpoena requested "[a]ny and all protocols relating to Epogen administration to patients" at certain identified facilities. (Def. Ex. 147.) The subpoena referred only to documents "received, dated, referred to, or created at any time during the period of October 1, 2001 through December 31, 2004." (*Id.* at 5.) Fresenius eventually responded to the subpoena in July 2008.

The government declined to intervene and Woodard's second amended complaint was unsealed on July 6, 2009. Woodard ultimately abandoned his claims against Fresenius and voluntarily dismissed Fresenius from the lawsuit, with the Government's consent, in January 2010.

7. State Medicaid Investigations

In January 2006, New York Medicaid Fraud Control Unit (the "Unit") began an investigation of Fresenius's and other providers' operations, including overfill billing. (Def. Ex. 9 ("2015 Kembel Decl.") ¶ 55.) Fresenius made a presentation regarding overfill in February 2006. (Def. Ex. 149.) The presentation explained that Fresenius's cost report submissions factor in the effect of overfill on Fresenius's per-unit Epogen costs. Although the presentation refers to overfill practices generally, and specifically discusses overfill practices in 2004 and earlier, the presentation does not address the ASP methodology or

whether Fresenius altered its cost reporting or billing practices after the ASP methodology was instituted in 2006. Following the presentation, the Unit dropped its investigation into Fresenius's overfill practices.

In May 2008, Fresenius responded to a request from an attorney for Wisconsin Medicaid regarding, *inter alia*, Fresenius's acquisition costs for Epogen and Zemplar. (Def. Ex. 90.) Fresenius provided data for 2002 and 2003 and noted that "[t]he company may also use overfill amounts contained in some vials, which also has the effect of reducing per-unit cost." (*Id.* at 4.) Fresenius further noted that "[c]harges to Medicare were reduced to the Medicare allowable." (*Id.*)

F. MedPAC Presentations

Fresenius made yearly presentations to MedPAC, a Congressional agency that advises Congress on Medicare. In a 2004 report, Fresenius discussed the impact of any decrease in the amount of Epogen overfill in a vial on Fresenius's yearly costs and profitability. (Def. Ex. 133 at 22.) In 2008, Fresenius's report, drafted by McGorty, included average Epogen costs associated with in-center treatments. (Def. Ex. 134 at 13.) It is not clear from this report whether overfill was taken into account in reporting these costs. Defendant asserts that the costs in this report were calculated using cost report data submitted to OIG, which McGorty testified accounted for the impact of overfill. (Def. SUMF ¶ 433.) But the report itself, (Doc. 134), does not make this clear. A third report, produced by the Kidney Care Council (a dialysis industry group) in December 2006, provided

to MedPAC acquisition cost data for 2005 "[n]et of overfill." (Def. Ex. 151, Appx. A.) "This method," the report explained, "represents the most accurate way to characterize the acquisition costs for Epogen." (*Id.*) The report also recognized that dialysis centers were, in 2005, billing Medicare for overfill. (*See id.*)

G. SEC Filings

From 2005 through 2010, Fresenius filed disclosures with the Securities and Exchange Commission ("SEC") noting that Fresenius bills the government for administered Epogen and that Fresenius uses Epogen overfill. (*See* Def. Ex. 116 ("2013 McGorty Decl.") ¶ 34; Def. Ex. 128 ("2006 SEC From 20-F") at 3 (noting that a "reduction by the manufacturer of [Epogen and similar drugs] of the amount of overfill in the . . . vials" could "adversely affect" business).)

For example, for fiscal year 2007, Fresenius included in its SEC filing a section addressing Medicare reimbursement with a heading entitled, "A reduction in reimbursement for or a change in the utilization of EPO could materially reduce our revenue and operating profit. An interruption of supply or our inability to obtain satisfactory terms for EPO could reduce our revenues." (2013 McGorty Decl. Ex. 11, Doc. 221-29 at 113-1117.) Under this heading, Fresenius disclosed the following:

> Our contract with Amgen USA, Inc., a subsidiary of Amgen, Inc.[,] covers the period from October 1, 2006 to December 31, 2011. Pricing is based on Amgen's list price and is subject to change within certain parameters. An increase in Amgen's price for EPO without a corresponding and timely increase in reimbursement for EPO by the Centers for Medicare and Medicaid Services ("CMS"), a reduction in the current overfill amount in EPO vials which we currently use (liquid medication, such as EPO, typically include a small overfill

> amount to ensure that the fill volume can be extracted from the vial as administered to the patient), or an interruption of supply could reduce our revenues from, or increase our costs in connection with, the administration of EPO, which could materially adversely affect our business, financial condition and results of operations.

(*Id.*)

H. TrailBlazer

TrailBlazer Health Enterprises, LLC ("TrailBlazer") was, during the relevant time period, a Medicare fiscal intermediary which processed claims for Medicare beneficiaries including Fresenius. On October 28, 2005, Fresenius's outside counsel Larri Short at Arent Fox faxed David Kembel a copy of a TrailBlazer document entitled "Drug Wastage" which she received in connection with her representation of a non-nephrologist physician client. (*See* Relator Ex. 8; Def. Ex. 201; 2015 Kembel Decl. ¶ 46, Doc. 221-6.) The document appears to be a draft TrailBlazer policy. The policy explained that TrailBlazer would "consider coverage of the billed amount of a drug that is reasonable and necessary for the patient's condition." (Def. Ex. 201 at 2.) The document recognized, however, that "if a provider must discard the remainder of a vial after administering a portion to a Medicare patient, the Medicare program may cover a small, but reasonable amount of discarded drug along with the amount administered." (*Id.*) But the document urged providers to minimize waste. (*Id.*)[20]

[20] Fresenius objects to Relator's reliance on the TrailBlazer policy document as hearsay. The Court does not rely on this document as a statement of TrailBlazer policy but instead only notice to Fresenius that a Medicare intermediary may have taken the position TrailBlazer appeared to

Although the 2005 TrailBlazer document appears to only address billing for drugs that are not administered (i.e. wastage), the document seems to go further to prohibit billing for overfill that is actually administered. "Total drug amounts billed as administered and/or wasted should not exceed the labeled amount contained in the vial(s)," the report directed. (*Id.*) The report warned that the "extra amount" of drug contained in the vial as overfill "must not be billed to Medicare since it does not represent an expense to the provider. The amount billed as 'wasted' must not be administered to another patient or billed again to Medicare." (*Id.*) The TrailBlazer document then provided tips for avoiding wastage and billing for wastage, followed by several examples of how to bill for wastage.

David Kembel learned from Ms. Short that TrailBlazer interpreted this policy to preclude billing for any overfill, whether wasted or administered, because TrailBlazer believed "the use of overfill conflicts with Average Sales Price reimbursement." (Relator Ex. 8; *see also* 2014 Kembel Dep. at 158, Doc. 220-3.) On November 1, 2005, Kembel emailed Fresenius's then general counsel Ron Kuerbitz, another Fresenius attorney Doug Kott, a lawyer who was part of Fresenius's Government Relations Group Kathleen Smith, and Fresenius's Chief Compliance Officer Todd Kerr. (Relator Ex. 8.) Kembel explained that he had spoken with Larri Short about this TrailBlazer publication, and Short provided additional information over the phone including that TrailBlazer was considering

have taken. The record contains no competent evidence that TrailBlazer actually implemented the policy expressed in its 2005 draft policy regarding billing for overfill administration.

expanding the policy to ESRD clinics and that TrailBlazer did in fact interpret "the policy to preclude billing for any overfill." (*Id.*) According to Kembel, Ms. Short's "conversations with TrailBlazer (for a non-nephrologist physician client) made it clear to her that TrailBlazer thinks the use of overfill conflicts with Average Sales Price reimbursement." (*Id.*)

Kembel stated that he did not know whether the policy would apply only to Epogen, "which is reimbursed by statute, or only other drugs like Zemplar." (Relator Ex. 8.) In his 2014 deposition, he clarified that, by "reimbursed by statute," he was referring to the fact that the specific statutory provision governing reimbursement for Epogen had at some point provided the actual, fixed dollar amount per thousand units administered. (2014 Kembel Dep. at 149-150.) At the time Kembel sent this email, however, both Epogen and Zemplar were reimbursed based on the average acquisition cost. *See* 42 C.F.R. § 414.904(d)(2)(i) (providing that drugs like Epogen and Zemplar would be reimbursed based on "acquisition cost" in 2005 and average sales price in 2006 and beyond). It is not clear from the portions of the record the parties rely upon whether, in 2005, Kembel simply misremembered that by that time, Epogen was no longer reimbursed by an actual, fixed dollar amount, or whether Kembel's 2014 deposition testimony inaccurately explained the meaning of his 2005 email.

In any case, as far as Kembel understood, the TrailBlazer policy detailed in the 2005 document did not apply to ESRD facilities, but TrailBlazer was considering expanding the policy to ESRD facilities. (*See* Relator Ex. 8.) Kembel

suggested putting "together a group to consider this issue and respond to TrailBlazer." (*Id.*) He closed by explaining that if the policy were to be applied to ESRD facilities, it "would do nothing but increase costs to the Medicare program, since for example the OIG's audit reports in their pricing recommendations presume a facility uses and bills for overfill."

Fresenius's counsel discussed the TrailBlazer policy among themselves and with Fresenius executives. Initially, Fresenius's Co-CEO Mats Wahlstrom considered the policy to be a "major issue." (Relator Ex. 32.) Fresenius's outside counsel, Larri Short, then advised that the TrailBlazer proposal went "well beyond the policy on drug wastage and overfill usage in the CMS Claims Processing Manual." (Realtor Ex. 30. at 1; *see, e.g.*, Relator Ex. 33 (May 25, 2007 CMS Manual System, Pub 100-04 Medicare Claims Processing) at 5 (addressing "Discarded Drugs and Biologicals" and providing only that "the program provides payment for the amount of drug or *biological* discarded along with the amount administered, *up to the amount of the drug or biological as indicated on the vial or package label*"); 2004 Medicare Claims Processing Manual, Chapter 17, Section 40, Doc. 251-1.)

Short also confirmed in an email to Kathleen Smith that, while TrailBlazer had adopted the policy "on the carrier side to physician practices," it was not clear whether it was applying the policy to ESRD facilities as well. (*Id.*) She recommended contacting TrailBlazer for a "status update." And Short advised that the policy "merits CMS intervention to address the complex realities of

multi-dosing out of single-dose vials and the inevitability of overfill usage when dialysis centers and physicians consistently do so." (*Id.*) But Short indicated that Fresenius would "need to know with certainty whether TrailBlazer is applying or intends to begin applying the policy to [its] ESRD facilities" before Fresenius has a "reasoned dialogue" with CMS about this policy. (*Id.* at 2.) Short stated in her 2015 declaration that she never understood or advised Fresenius that it was impermissible to bill for overfill for drugs reimbursed under the ASP methodology or that CMS did not consider overfill as an expense for purpose of Medicare billing. (Def. Ex. 233 ("Short Decl." ¶ 9.)

Kembel considered responding to TrailBlazer, but he does not recall following up on the TrailBlazer document. (Relator Ex. 8; 2014 Kembel Dep. at 180-81.) Kembel testified that he did not ask for an opinion from Arent Fox or any other attorney about the impact of ASP on billing or overfill actually administered. (2014 Kembel Dep. at 160.)

Kembel testified, however, that TrailBlazer "never implemented this policy for dialysis facilities." (*Id.* at 152.) This testimony is consistent with the record. Relator has identified no evidence to suggest TrailBlazer ever promulgated a policy prohibiting ESRD clinics from billing for overfill actually administered, and at oral argument, Relator's counsel confirmed that the record contains no such evidence.[21] TrailBlazer is no longer in the Medicare intermediary business.

[21] Relator's counsel confirmed at oral argument that Relator's counsel did not take a deposition of someone who could speak on behalf of TrailBlazer, which is no longer in the Medicare intermediary business.

(Def. Ex. 205 ("Walker Decl.") ¶ 6.) Fresenius's counsel thus issued a subpoena for records on the entities that maintain TrailBlazer's records, seeking any document "formerly in the possession of TrailBlazer . . . relating or referring to the practice of administering or billing for overfill contained in vials of injectable medications by End-Stage Renal Disease facilities." (Def. Ex. 206 ("H. Bennett Aff.") ¶ 3.) Fresenius's counsel received no such documents in return. The TrailBlazer "End Stage Renal Disease Manual" published in 2008 and 2010 did not incorporate any prohibition against billing for administered overfill. (*See* Def. Ex. 221 (2010 TrailBlazer ESRD Manual), Doc. 221-48 at 187 (addressing the "Discarded Drugs and Biologicals" policy but was silent as to billing for overfill actually administered); Def. Ex. 232 (2008 ESRD TrailBlazer Manual), Doc. 233-2 (silent as to billing for overfill actually administered).) That TrailBlazer never extended the policy to ESRD clinics suggested to Kembel that the government agreed that billing of overfill was appropriate, and he advised Fresenius accordingly. (*See id.*)[22]

[22] Fresenius directs the Court to Kembel's 2015 declaration, in which he vaguely explains that Fresenius clinics in Albuquerque were subjected to a 2006 audit. (Def. Reply at 14, Doc. 236; Def. Ex. 9 ("2015 Kembel Decl.") ¶¶ 51-53.) Among other actions as a result of the audit, TrailBlazer denied claims for reimbursement because Fresenius had failed to document wastage of Epogen. (2015 Kembel Decl. ¶ 52; *see* 2015 Kemble Decl. Ex. U, Doc. 221-8 at 4.) In a February 2008 appeal of this decision, Fresenius explained that it did not discard the contents of single-dose vial because Fresenius re-entered these vials to extract the "remaining drug product." (2015 Kemble Decl. Ex. U; *id.* Ex. V ("Woodruff Decl.") ¶ 6.) Kembel attests that by representing that Fresenius uses all the contents of the vial, TrailBlazer would have understood that it uses and bills for overfill. (*See* 2015 Kembel Decl. ¶ 53.) And according to Kembel, as a result of the appeal, TrailBlazer paid all disputed claims. (*Id.* ¶ 54.) This evidence supports the reasonable inference that Kembel believed TrailBlazer did not prohibit billing for overfill that was actually administered. The Court disagrees that this evidence shows that TrailBlazer in fact approved of billing for administered overfill because the appeal documents Kembel attaches to his declaration do not address overfill in any manner and instead only addressed Fresenius's

In 2007, TrailBlazer again addressed ESRD wastage in a document which appears to be another draft TrailBlazer policy, and which Fresenius received. (Relator Ex. 34.)[23] This document reiterated that, although providers could bill Medicare for wastage for drugs priced through the ASP program, providers could not bill for wasted overfill. "If a physician, hospital or other provider must discard the remainder of a single-use vial or other single-use package after administering a reasonable amount of drug/biological to a Medicare patient, the program provides payment for a reasonable amount of drug/biological discarded along with the amount administered up to the amount of the drug or biological indicated on the vial or package label." (*Id.* at 1.) TrailBlazer explained that in this wastage context, the overfill — "[the] extra amount of drug in each vial to account for the wastage in syringe hubs" — "must **not** be billed to Medicare since it does not represent an expense to the provider and clearly exceeds the amount on the vial or package label." (Relator Ex. 34 at 1.) Relator acknowledges that this 2007 document specifically warned providers not to "bill for overfill when they billed for drug wastage." (Relator SUMF ¶ 32; *see also* Warren Dep. at 272-

practice of reentering vials of Epogen to avoid wastage. While a jury could infer from this that TrailBlazer understood Fresenius was extracting and administering overfill and billing Medicare for this administration, a reasonable jury could also decide that the TrailBlazer audit and Fresenius's appeal simply did not speak to overfill administration.

[23] It is not clear whether the policies in this document were ever implemented. At oral argument, Relator explained that it was not offering this or the 2005 TrailBlazer policy document as evidence of TrailBlazer's actual policy, but instead only as evidence that Fresenius was put on notice that a fiscal intermediary may have taken the positions appearing in these policy documents. Fresenius admits it received "some" of these policy documents. (Kembel Dep. at 116-117.)

273 (testifying that the TrailBlazer policy published in a 2005 document "speaks to the billing for wasted drugs in general").)

While the 2005 TrailBlazer document states that billing for overfill "*administered* and/or wasted" was prohibited, the 2007 TrailBlazer document does not mention overfill *actually administered*. (*See* Def. Ex. 233 ("Short Decl.") Ex. A at 2.) In other words, TrailBlazer's 2007 document appears to have deleted the reference to overfill "administered" and thus only addressed the prohibition against billing for overfill if discarded; the policy did not separately address billing for overfill actually administered. Fresenius did not bill for overfill in this wastage context, i.e. if the overfill was discarded. (2014 Kembel Dep. at 154.) The following chart compares the overfill policies presented in the 2005 and 2007 TrailBlazer documents, showing that the policies are the same as to wastage (medicine not administered up to the labeled amount on the vial) and unused overfill (medicine above the labeled amount on the vial), but appear to somewhat differ as to *administered* overfill.

Policy	2005 Document	2007 Document
Wastage	Can bill for wastage (i.e. medicine not administered, up to the labeled amount on the vial)	Can bill for wastage (i.e. medicine not administered, up to the labeled amount on the vial)
Unused Overfill	Cannot bill for overfill (i.e. amount over the labeled amount on the vial) if overfill is thrown away	Cannot bill for overfill (i.e. amount over the labeled amount on the vial) if overfill is thrown away
Administered Overfill	Apparently cannot bill for overfill even if it is actually administered	Silent as to billing for overfill if administered

I. The 2010 Rule

In 2010, CMS proposed a rule that would explicitly prohibit overfill billing. (*See* above Part II.C.) The proposal recognized that providers were utilizing and billing Medicare for overfill that they received for free. It then recognized the "longstanding Medicare policy that in order to meet the general requirements for coverage under the 'incident to' provision, services or supplies should represent an expense incurred by the physician or entity billing for the services or supplies." (Def. Ex. 208 at 3.) *See also* 75 Fed. Reg. 40040, 40155 (July 13, 2010) ("It has been longstanding Medicare policy that in order to meet the general requirements for coverage under the 'incident to' provision, services or supplies should represent an expense incurred by the physician or entity billing for the services or supplies.") The proposal concluded,

> In accordance with our policy, providers may not bill Medicare for overfill harvested from containers, including overfill amounts pooled from more than one container, because that overfill does not represent a cost to the provider. . . . Because such overfill is not included in the calculation for payment limits under [the ASP methodology] and does not represent incurred costs to a . . . provider, we are proposing to update our regulations at 42 CFR part 414 Subpart J to clearly state that Medicare ASP payment limits are based on the amount of product in the vial or container as reflected on the FDA-approved label.

(*Id.* at 3-4.)

Fresenius's outside counsel, Lisa Estrada at Arent Fox, reviewed CMS's proposal and sent it to David Kembel. (*Id.* at 1.) She introduced the proposal by stating, "It isn't applicable to EPO in ESRD I think — but still worth reading." (*Id.*)

Mr. Kembel responded that the rule was not "directly related to [Fresenius] after the bundle" — referring to the fact that starting 2011, Fresenius would opt-in to a bundle payment methodology in which overfill billing was permitted. (*Id.*) Kembel added however that "the whacky theory could spread to other federal payors who line item bill." (*Id.*) He later elaborated about the proposed rule, characterizing it as a "trifecta of poor policy" which would increase costs, decrease efficiency, and create an unworkable tracking system. (Def. Ex. 209.) He also opined that the proposed rule was "simply a backdoor way to memorialize a legal theory that never worked anyway." (*Id.*) Kembel viewed this proposal as a change in existing policy that did not apply to Fresenius going forward. (*See id.*; *see also* Def. Ex. 210; Def. Ex. 211.)

Around this time, Jonathan Blum, the Deputy Administrator for CMS, confirmed that it had never previously issued a policy on the topic of overfill. (Def. Ex. 33.) In a letter dated June 17, 2010, Blum, stated that CMS's policy had been to "reimburse suppliers for the total number of units administered to a Medicare beneficiary assuming that the beneficiary's receipt of a drug is reasonable and necessary." (*Id.* at 3.) He confirmed that CMS did "not make payment determinations based on the absence or presence of 'overfill' in a vial." (*Id.*)[24]

[24] Relator objects to this statement, not because it is inaccurate, but because it fails to tell the full story. According to Relator, while it is true that CMS had no policy explicitly prohibiting the billing of overfill, as the Court has already found, the combination of implicit principles and regulatory provisions made it impermissible to bill for overfill administration.

As to the "longstanding policy" of Medicare to require an expense before authorizing any reimbursement, Fresenius understood this policy to refer only to drugs reimbursed as an "incident to" the physician's services. (Relator Ex. 19 at 974.) Fresenius did not believe that the "incident to" rules applied to dialysis facilities, (*id.*), and as the Court explains in Parts II and V, these "incident to" rules in fact did not apply to such facilities. (*See also* Relator SUMF ¶ 21 (providing evidence that CMS witnesses understood that Medicare had a longstanding policy of prohibiting physicians from billing for overfill because overfill did not represent an expense to them).)[25] Thus, Fresenius maintains that when it learned of the 2010 proposed rule, it believed that its practice of billing for overfill was still permissible, even if it incurred no expense related to the overfill.

J. CMS's Knowledge

The evidence suggests that CMS was aware that Fresenius and others were billing for administered overfill and yet took no action to curb the practice. In particular, the testimony of two CMS Rule 30(b)(6) designees suggests that CMS was fully aware that overfill billing was occurring. First is the testimony of John Warren, the former director of the Division of Ambulatory Services at the Center for Medicare Management. It was in fact Mr. Warren's division at CMS that

[25] Relator asserts that the evidence cited in paragraph 21 of his SUMF also proves CMS's understanding that overfill billing was prohibited by dialysis facilities as well. The evidence Relator cites only supports the proposition that CMS's 2010 rule clarified its existing position regarding drugs reimbursed "incident to" a physician's services. (*See, e.g.*, Hartstein Dep. at 88-90).

drafted the policy which ultimately became the 2011 rule prohibiting overfill billing. Mr. Warren testified as the government's corporate representative on overfill-related issues. Mr. Warren confirmed that CMS, "with full knowledge of the fact that it was a regular practice that providers were billing for overfill[,] undertook no effort to curtail that practice until [the 2010] regulation." (2012 Warren Dep. at 116.) In particular, Mr. Warren testified that, if OIG or CMS identifies conduct that it believes is fraudulent in one of its inquiries, it should take action. (*Id.* at 64-65.) But Warren agreed that, at no point in time did CMS ever take action to bring an enforcement proceeding or to suggest an enforcement proceeding would be appropriate regarding outpatient dialysis facilities' use of billing for overfill prior to January 1, 2011. (*Id.* at 65.) To be more explicit, as far as Warren is aware, CMS never informed any dialysis facility company like Fresenius that billing for overfill was against Medicare rules or regulations, prior to the proposed 2010 rule. (*See id.* at 115-116) Relator has identified no evidence to the contrary in the record.

An additional CMS corporate designee, Marc Hartstein, testified in a similar manner.[26] Hartstein agreed that, to his knowledge, CMS never put a provider on notice, prior to January 1, 2011, that there would be something wrong with submitting a claim for a separately billable administered dialysis drug that

[26] Harstein has worked for CMS since the late 1980s. At the time of his deposition in 2014, Hartstein was the Director of Hospital and Ambulatory Policy, and as such, was involved with how Medicare pays for Part B drugs, including drugs for ESRD. Specifically, his department was responsible for establishing payment policy related to Part B drugs. He did not, however, have responsibility for administering the ESRD program. (Hartstein Dep. at 8, 10, 12.)

included overfill. (Hartstein Dep. at 21, 32-33, Doc. 220-1.) And he confirmed that during the relevant time period, CMS instructed providers to bill for all units of drug administered to Medicare beneficiaries, but did not explicitly instruct providers to exclude overfill from this instruction. (*Id.* at 37-39.) He also explained that the 2006 adoption of the ASP methodology for ESRD drugs did not change CMS's policies about which units were reimbursable. (*Id.* at 49.) And according to Hartstein, in 2009, he personally became "aware that [CMS was] being billed for overfill for which the provider or supplier did not have a cost." (*Id.* at 45.) He could not speak to when others in CMS became aware of this practice but suggested that once CMS learned that clinics were billing for overfill, CMS "made an explicit determination or explicit clarification to [its] policy [in 2010], that it is not permitted to bill for overfill, because the provider does not have a cost." (*Id.*)

The record contains one piece of evidence suggesting that CMS may not have been fully aware that dialysis centers were billing for administered overfill. In its published introduction to the final 2011 rule, CMS expressly stated that it did not believe "inappropriate billing" of administered overfill "occur[red] routinely." 75 Fed. Reg. 73170, 73467 (Nov. 29, 2010). At oral argument, Fresenius's counsel argued that this statement in the proposed final rule was referring only to reentry into "single-use vial[s]," 75 Fed. Reg. 73170, 73467 (Nov. 29, 2010), and not to utilization and billing for overfill in multi-use vials. The Court, however, views the record in the light most favorable to the Relator and

credits that this statement in the federal register is suggestive that CMS may not have know that inappropriate overfill billing was occurring on a routine basis.

K. Expert Testimony

Several experts testified regarding Fresenius's overfill practices. Brady Augustine, a former Senior Advisor to the CMS Administrator who oversaw ESRD issues, testified as an expert on behalf of Fresenius. Augustine explained that "use and billing for overfill was widespread industry practice and known to CMS at all relevant times." (Def. Ex. 36 ("Augustine Expert Report") at 21-22.) He further explained that "dialysis facilities openly discussed their use and billing of overfill and expressed concern that if they provided EPO to patients without billing for it, it could be considered an inducement." (*Id.* at 22.) According to Augustine, until the publication of the final overfill rule effective January 1, 2011, "neither the dialysis industry nor its regulators believed that overfill was a 'free good' that was not reimbursable by CMS." (*Id.* at 21.) *But see* 75 Fed. Reg. 73170, 73466-73467 (suggesting that even before the 2011 rule, providers could "not bill Medicare for overfill harvested from single use containers, including overfill amounts pooled from more than one container, because that overfill does not represent a cost to the provider").

Fresenius also proffered as an expert, Kevin McAnaney, former Chief of the Industry Guidance Branch of OIG,[28] who explained that there was a "consensus

[28] McAnaney was the Chief of the Industry Guidance Branch of OIG from 1997 through 2003 and has since regularly counseled health care entities including CMS regarding FCA and

view among experienced health care counsel, industry participants, and regulators at the time" from 2003 through 2010 that overfill was properly billable. (Def. Ex. 40 ("McAnaney Report") at 1, 3.) McAnaney also agreed that it "would not have been reasonable for Fresenius to administer overfill without billing for it" as such practice could run afoul of 42 U.S.C. § 1320a-7a(a)(5), "prohibiting the offer or transfer of remunerations to Medicare . . . enrollees that is likely to influence their choice of providers or suppliers." (*Id.* at 3.)

Dr. James Alexander, former Medical Director for Medicare contractor TrailBlazer Health Enterprises, LLC from 1994 to 2002, then testified as Relator's expert. Even Alexander agreed that "it is appropriate for Fresenius to use and bill for overfill as long as it does it on the same shift with the same patients and properly administer the exact amount of drug that the doctor wants." (Alexander Dep. at 292-293, Doc. 222-3.) Relator does not contest that his expert testified in this way. (*See* Relator Resp. Def. SUMF ¶¶ 70-71, Doc. 231.)[30]

compliance issues related to discounts and the discount statutory and regulatory exceptions. (Def. Ex. 40 at 1.)

[30] At oral argument, Relator's counsel attempted to minimize the fact that his own expert testified that in certain clinical circumstances, overfill administration was reimbursable, by arguing that Dr. Alexander was only addressing the limited situation of utilizing overfill "on the same shift with the same patients." (*See* Alexander Dep. at 293.) Relator's counsel did not explain what difference that would make, particularly when Relator argues that overfill billing was impermissible in all contexts. Relator's counsel further argued that there was a difference between billing for overfill and retaining the proceeds. But again, Relator's claim here is based on the request for reimbursement for overfill actually administered, the precise scenario Dr. Alexander testified would have been permissible.

IV. FRESENIUS'S MOTION FOR SUMMARY JUDGMENT

"To establish a cause of action under the False Claims Act, a relator must prove three elements: (1) a false or fraudulent claim; (2) which was presented, or caused to be presented, by the defendant to the United States for payment or approval; (3) with the knowledge that the claim was false." *United States ex rel. Walker v. R&F Props. of Lake County, Inc.*, 433 F.3d 1349, 1355 (11th Cir. 2005) (citing 31 U.S.C. § 3729(a)).

Although the pending cross-motions for summary judgment primarily address the "knowledge" element of the FCA claim, Fresenius also argues that the requests for reimbursement for overfill administration were not "false."[31] The Court briefly addresses Fresenius's argument regarding falsity and then turns to the issue of Fresenius's intent.

A. Falsity

Fresenius moved anew for summary judgment on the first element of Relator's FCA claim: falsity. The Court previously ruled that from 2006 through 2010, Fresenius's requests for reimbursement for the provision of overfill represented a "false" claim under 31 U.S.C. § 3729(a). *United States ex rel. Saldivar v. Fresenius Medical Care Holdings, Inc.*, 972 F. Supp. 2d 1339, 1357-

[31] Fresenius also moves for summary judgment on two other issues: materiality and damages. The Court need not address these issues in light of its holding that Relator has failed to prove Fresenius submitted a false claim "knowingly."

58 (N.D. Ga. 2013). The Court left open the issue of falsity for calendar year 2005. *Id.* at 1353, n.17.[32]

Fresenius now argues that for "the entire period at issue in this case" — 2005 through 2010 — Fresenius's overfill billing practices did not constitute false claims as a matter of law. Fresenius reasserts its argument from the first round of summary judgment briefing that "[n]o provision of the Social Security Act or implementing regulations defines overfill as free or states that goods that were acquired for free by an ESRD provider but that are billed to ESRD patients cannot be reimbursed by Medicare." (Fresenius's Memo. Supp. Mot. Summ. J. at 31, Doc. 221-1.) And Fresenius now offers more "developed" evidence that it believes proves CMS's interpretation of the relevant statutes and regulations is consistent with its own.

The Court will not reconsider its previous decision regarding the falsity element of Relator's claims for the years from 2006 through 2010 and declines to decide whether overfill billing was permissible in 2005, for two reasons. First, while Fresenius has this time around argued more convincingly that the Medicare rules and regulations applicable at the time simply did not prohibit overfill billing, Fresenius's arguments still seem to fall short. It is true that before January 1, 2011, the relevant Medicare rules and regulations did not expressly provide that billing for overfill was prohibited. But as the Court explained in its

[32] Relator does not contend that overfill billing was prohibited before 2005 when certain Part B drugs were reimbursed based Average Wholesale Price ("AWP") because at that time, it was not clear whether AWP reimbursement took overfill into account. (Relator Resp. at 10, Doc. 230.)

Order on the parties' first cross-motions for summary judgment, the idea that a provider cannot bill Medicare for items it did not itself pay for is derived from the overall statutory and regulatory structure of Medicare, and from general prohibitions against reimbursement for free goods, such as free samples. And at least beginning in 2006, the method for calculating the Average Sales Price, excluding overfill as a cost to providers, implicitly indicates that overfill is not an item providers pay for, as far as Medicare reimbursement is concerned. Thus, although no express rule or policy statement prohibited overfill billing, the relevant Medicare rules and regulations still do not seem to authorize overfill reimbursement, at least from 2006 through 2010.

Second, even if the Court were to reconsider its initial falsity decision or decide the falsity element for 2005, such decision would have no effect on the final disposition of this case. As the Court explains next, because the Medicare rules and regulations proscribing ESRD drug reimbursement were not simply ambiguous, but silent as to overfill billing, and because, *inter alia*, Fresenius's interpretation was reasonable in light of all the evidence, no reasonable jury could find that Fresenius "knowingly" submitted false claims. *See United States ex rel. Hixson v. Health Mgmt. Sys., Inc.*, 613 F.3d 1186, 1190 (8th Cir. 2010) (declining to decide whether the defendant correctly interpreted a statute because the defendant had not acted with the requisite state of mind to support

an FCA claim).[33] In other words, Relator failed to marshal sufficient evidence for a reasonable jury to find Fresenius acted recklessly.

B. Knowledge

A false claim against the government does not constitute a violation of the False Claims Act unless the false claim is presented to the Government with knowledge that the claim is false. *See United States ex rel. Walker v. R&F Props. of Lake County, Inc.*, 433 F.3d 1349, 1355 (11th Cir. 2005) (citing 31 U.S.C. § 3729(a)); *McNutt ex rel. United States v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1259 (11th Cir. 2005) ("The False Claims Act does not create liability merely for a health care provider's disregard of Government regulations or improper internal policies unless, as a result of such acts, the provider knowingly asks the Government to pay amounts it does not owe." (quoting *Clausen*, 290 F.3d at 1311)).

Under the FCA, "knowingly" "means that a person, with respect to information (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A); *accord Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1058 (11th Cir. 2015). The false information at issue in a False Claims Act case may be factual or legal in

[33] The Court also notes that, had it been presented with this full record on the first round of summary judgment briefing, the Court would likely have declined to consider the falsity element of Relator's FCA claim in the first place. Indeed, if a rule or regulation proscribing certain conduct is ambiguous — or in this case, silent — and the defendant's proffered interpretation of the rule is reasonable, a court is hard-pressed to find that defendant acted knowingly, absent clearer evidence of the defendant's intent.

nature. *See United States v. R&F Props. of Lake Cnty., Inc.*, 433 F.3d 1349, 1357-58 (11th Cir. 2005); *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 304-305 (3d Cir. 2011).

A classic example of a factually false claim would be a request for reimbursement for services not actually administered. *See, e.g.*, *United States ex rel. Hockett v. Columbia/HCA Helathcare Corp.*, 498 F. Supp. 2d 25, 64 (D.D.C. 2007) (providing as an example of a factually false claim where an invoice "states that patient X stayed for five days when he really stayed for three"). Factually false cases are "fairly straightforward." *United States ex rel. Phalp v. Lincare Holdings, Inc.*, --- F. Supp. ---, 2015 WL 4528955, at *12 (S.D. Fla. July 10, 2015) ("A factually false claim occurs, for example, when a supplier submits a claim that misidentifies the goods supplied or requests reimbursement for goods that it never provided.").

Legally false claims, on the other hand, typically arise in the context of a false certification claim wherein a "claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment." *Wilkins*, 659 F.3d at 305; *see, e.g.*, *McNutt ex rel. United States v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1259 (11th Cir. 2005); *Phalp*, 2015 WL 4528955, at *13-14. A false certification may be express, as when, for example, "the supplier has certified compliance with applicable laws and regulations as part of the claims submission process." *Phalp*, 2015 WL 4528955, at *13 (citing *United States ex rel. Keeler v. Elisai, Inc.*, 568 F. App'x

783, 798 (11th Cir. 2014)). A false certification may also be implied "where compliance with a law, rule, or regulation is a prerequisite to payment but a claim is made when a participant has engaged in a knowing violation." *Keeler*, 568 F. App'x at 799.

The alleged FCA claim here appears to be based both on factually and legally false information. The claim arguably involves an alleged factually false, implied representation that Fresenius paid for the Epogen and Zemplar it administered, when in fact the overfill was, as a matter of fact, free. But Relator's claim more clearly alleges an implied false certification that the Epogen and Zemplar overfill administered was legally reimbursable. For this reason, the Court finds that Relator's FCA claim is more analogous to impliedly false claims. *See United States v. Calhoon*, 97 F.3d 518, 529 (11th Cir. 1996) (holding that evidence of the "filing of reports intended and designed to deceive and mislead the auditors for the purpose of obtaining reimbursement of costs [the defendant] knew to be at least presumptively, if not clearly, nonreimbursable" is sufficient to prove falsity); *In re Cardiac Devices Qui Tam Litigation*, 21 F.R.D. 318, 347 (D. Conn. May 12, 2004) (holding that "defendants [which] knowingly submitted claims for payment of non-covered services provided in connection with investigational devices that were not reasonable and necessary" violate the FCA). The Court will therefore analyze the knowledge element of Relator's FCA claim by considering whether Fresenius submitted claims for payment of overfill

administration knowing (or recklessly disregarding) that overfill was not reimbursable under the Medicare rules and regulations.

The Court first considers whether Relator has marshaled sufficient evidence for a showing of recklessness, which is a "lesser scienter showing" than "actual knowledge" or deliberate ignorance. *See Urquilla-Diaz*, 780 F.3d at n.15 (noting that the deliberate ignorance scienter requirement "plainly demands even more culpability than that needed to constitute reckless disregard."); *United States ex rel. Parikh v. Brown*, 587 F. App'x 123, 129 (5th Cir. 2014) (recognizing that in an FCA case, recklessness is a "lesser scienter showing" than actual knowledge); *United States ex rel. Ervin & Assocs., Inc. v. Hamilton Securities Grp., Inc.*, 370 F. Supp. 2d 18, 50 (D.D.C. 2005). Because the record is insufficient to support a finding of recklessness, the Court only briefly addresses Relator's argument that Fresenius had actual knowledge that overfill reimbursement was impermissible and does not consider whether there is evidence of deliberate ignorance.

1. Recklessness

To prove recklessness, a False Claims Act plaintiff must come forward with evidence of an "aggravated form of gross negligence." *Urquilla-Diaz*, 780 F.3d at 1057. "Congress did not intend to turn the False Claims Act, a law designed to punish and deter fraud . . . into a vehicle either punish[ing] honest mistakes or incorrect claims submitted through mere negligence or imposing a burdensome obligation on government contractors rather than a limited duty to inquire." *Id.*

(internal citation omitted) (internal quotation marks omitted) (quoting *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1274 (D.C. Cir. 2010) (quoting S. Rep. 99–345, at 6, 19, 1986 U.S.C.C.A.N. 5266, 5271, 5284)); *accord United States ex rel. Parato v. Unadilla Health Care Ctr., Inc.*, 787 F. Supp. 2d 1329, 1339 (M.D. Ga. 2011) ("Innocent mistakes or negligence are not actionable, nor are imprecise statements arising from a disputed legal question.").

For example, in *Urquilla-Diaz*, the Eleventh Circuit held that the record could not support a finding of recklessness where the defendant took several good faith steps to ensure compliance. The relator alleged that Kaplan University falsely certified compliance with section 504 of the Rehabilitation Act, 29 U.S.C. § 794(a), and its implementing regulations prohibiting discrimination against individuals with disabilities. Relator provided evidence that Kaplan's nondiscrimination policies and procedures were inconsistent with section 504. But the record also contained evidence that Kaplan hired an experienced attorney to revise these polices, Kaplan based its policies on those previously approved by the EEOC, Kaplan held regular compliance trainings, and Kaplan hired outside counsel to review its training materials. This evidence showed that Kaplan University "took compliance with the Rehabilitation Act and its implementing regulations seriously" and thus "contradict[ed] [the relator's] contention that Kaplan's compliance certification was made with reckless disregard for the truth." *Id.*

In cases such as the one now before this Court involving a misinterpretation of statutory or regulatory requirements, courts assessing recklessness also consider whether the defendant's interpretation was reasonable. Courts may consider a variety of evidence including whether the defendant sought, received, and followed legal advice, whether the defendant acted in conformity with others in the industry, and whether the defendant reasonably believed that its interpretation was consistent with the government's. *See United States ex rel. Williams v. Renal Care Grp., Inc.*, 696 F.3d 518, 531 (6th Cir. 2012) (rejecting an assertion of recklessness based in part on the defendant's seeking legal advice from an attorney who in turn sought clarification on the rules from CMS officials); *United States ex rel. Hixson v. Health Mgmt. Sys., Inc.*, 613 F.3d 1186, 1190 (8th Cir. 2010) ("[A] statement that a defendant makes based on a reasonable interpretation of a statute cannot support a claim under the FCA if there is no authoritative contrary interpretation of that statute."); *United States ex rel. Williams v. Renal Care Grp.*, 696 F.3d 518, 531 (6th Cir. 2012) (holding that a defendant is not reckless when, in the face of ambiguous regulations, the defendant follows industry practice, consults and relies on advice of counsel, and was forthright with the government about its conduct); *K&R*, 530 F.3d at 983-84 (holding that where the defendant's understanding of a regulation is plausible and not unreasonable, the defendant does not act recklessly); *United States ex rel. Streck v. Allergan, Inc.*, 894 F. Supp. 2d 584, 595-96 (E.D. Pa. 2012) ("Plaintiff fails to plead sufficient facts that

[the defendants'] interpretation of the statutory and regulatory scheme was unreasonable, let alone that [the defendants'] interpretation raised 'the unjustifiably high risk of violating the statute necessary for reckless liability.'" (quoting *Safeco v. Burr*, 551 U.S. 47, 70)); *see also Safeco*, 551 U.S. at 70 n.20 ("Where, as here, the statutory text and relevant court and agency guidance allow for more than one reasonable interpretation, it would defy history and current thinking to treat a defendant who merely adopts one such interpretation as a knowing or reckless violator.") (discussing liability for willfully violating the Fair Credit Reporting Act, 15 U.S.C. § 1681n(a)).

On the other hand, a defendant's lack of diligence in the face of ambiguity could suggest recklessness. *See United States ex rel. K&R Ltd. Partnership v. Mass. Housing Fin. Agency*, 530 F.3d 980, 983-84 (D.C. Cir. 2008); *see also Heckler v. Community Health Servs. of Crawford Cnty., Inc.*, 462 U.S. 51, 63-64 (1984) ("As a participant in the Medicare program, respondent had a duty to familiarize itself with the legal requirements for cost reimbursement."); *United States v. Mackby*, 261 F.3d 821, 826-27 (9th Cir. 2001) ("By failing to inform himself of those requirements, particularly when twenty percent of [the clinic's] patients were Medicare beneficiaries, [the defendant] acted in reckless disregard or in deliberate ignorance of those requirements, either of which was sufficient to charge him with knowledge of the falsity of the claims in question.") (addressing recklessness where no ambiguity existed).

In *K&R*, for example, the Court of Appeals for the District of Columbia Circuit recognized that a defendant that fails to obtain a legal opinion on an ambiguous issue, when it had reason to do so, might be reckless. *K&R*, 530 F.3d at 983-84. In that case, however, the record contained nothing that would have warned the defendant against the view it took. In particular, there was no evidence that the regulating agency expressed any concern about the practice at issue. Thus, the defendant's failure to obtain a legal opinion did not suggest recklessness. *Id.*; *see also Seibert v. Gene Security Network, Inc.*, No. 11–cv–01987–JST, 2014 WL 6765835, at *7-8 (N.D. Cal. Dec. 1, 2014 (recognizing in an FCA action "the general principle that those who submit claims to the government for reimbursement may be acting in reckless disregard as to the truth or falsity of their submissions if they fail to take steps to confirm the accuracy of those submissions") (collecting cases in which defendants made little or no effort to familiarize themselves with the requirements or verify that their submissions were factually and legally justified); *United States v. Space Coast Med. Assoc., L.L.P.*, No. 6:13–cv–1068–Orl–22TBS, --- F. Supp. 3d ---, 2015 WL 1456122, at *8 (M.D. Fla. Feb. 6, 2015) ("Courts have found that even if a defendant submits a false claim, if the defendant's interpretation of a statute or regulation was reasonable, and 'if there is no authoritative contrary interpretation' of the rule, the relator cannot satisfy the knowledge requirement under the False Claims Act.") (quoting *Hixson*, 613 F.3d at 1190).

While reliance on the advice of counsel weighs against a finding of recklessness, courts also consider whether the defendant fully disclosed pertinent facts to its attorneys, whether the defendant fully implemented the attorneys' advice or instead failed to comply, and whether the attorney's advice was "patently unreasonable and thus not worthy of reliance." *United States v. Newport News Shipbuilding, Inc.*, 276 F. Supp. 2d 539, 565-66 (E.D. Va. 2003) (holding that the question of reliance on counsel "merits further factual inquiry at trial" because it was unclear whether the defendant followed the attorney's advice in good faith and whether the advice itself was reasonable in relation to the disputed legal question).

Likewise, while courts consider evidence suggesting that the government knew about the conduct at issue and failed to stop it, such evidence has its limits. *See Williams*, 696 F.3d at 531; *United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 953 (10th Cir. 2008); *K&R*, 530 F.3d at 983 (considering evidence that the defendant generally did not endeavor to hide the conduct that was the subject of the FCA claim and in fact brought a related, albeit somewhat different, issue to the regulating agency). In other words, evidence of government knowledge and acquiescence does not necessarily resolve the scienter issue. Instead, evidence of government knowledge — and more importantly the defendant's awareness of government knowledge — is simply an additional factor to consider when assessing whether the record supports a finding of recklessness. Where the government knew all relevant facts, discussed these with the defendant, but failed

to take action, the inference one can draw is greater than where the government was somewhat in the dark. *See, e.g.*, *United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 951-53 (10th Cir. 2008) (recognizing that most cases in which summary judgment is granted on the basis of government knowledge, "there has been more direct communication between the government and the contractor in the context of an existing contractual relationship" but holding that neither the directness of the communication nor its nexus to an existing contractual relationship is a predicate for the government knowledge inference); *Wang v. FMC Corp.*, 975 F.2d 1412, 1421 (9th Cir. 1992), overruled on other grounds, *United States ex rel. Hartpence v. Kinetic Concepts, Inc.*, --- F.3d ---, No. 12-55396, 12-56117, 2015 WL 4080739 (9th Cir. July 7, 2015).

In *Burlbaw*, for example, the record was insufficient for a finding of recklessness in part based on government knowledge and cooperation. *Burlbaw*, 548 F.3d at 949-60. There, New Mexico State University ("NMSU") allegedly falsely certified that it was a qualified for minority-institution status such that it was entitled to various United States Department of Defense ("DoD") contracts. Evidence in the record suggested that NMSU lacked the necessary data to determine its qualifications and failed to adequately track minority enrollment. The court held that this evidence could support a finding of negligence. But the court considered additional evidence that the defendant relied on a list of minority-institutions released by the United States Department of Education ("DOE") which identified NMSU, and additional undisputed evidence that the

DoD itself had relied on this list as well. The DoD in fact invited the university to apply for the contracts based on this very list. Relying in part on the evidence of governmental knowledge and governmental cooperation, the court found a "strong illation that defendants did not 'knowingly' submit false claims." *Id.* at 957.

Likewise the court in *Williams* held that a jury could not find the defendant, a dialysis provider, reckless in its decision to create a wholly-owned subsidiary so it could capitalize on a Medicare reimbursement loophole. *Williams*, 696 F.3d at 531. The court explained that industry publications openly encouraged this corporate structure and others in the industry employed it. *Id.* The defendant was also forthright with government officials about its structure, and thus CMS and OIG both knew about it. Under these circumstances, deeming the defendant's conduct reckless would "impose[] a burden on government contractors far higher than what Congress intended when it passed" the FCA. *Id.*

Considering the totality of the evidence in the light most favorable to the Relator, no reasonable jury could find that Fresenius acted recklessly in billing Medicare for overfill actually administered. To start, the relevant rules and regulations regarding ESRD drug billing were not simply ambiguous regarding overfill billing, they were silent.[34] *See Saldivar*, 972 F. Supp. 2d at 1349. Indeed, it is undisputed that no rule or regulation expressly prohibited billing for

[34] This is not to say that Medicare contractors have no obligation to digest the available rules and regulations to determine whether the drugs they administer are legally reimbursable. But the silence in the Medicare rules and regulations makes it harder for the Relator to prove recklessness.

administered overfill until 2011. The only Medicare rule or policy that expressly addressed overfill — the extra amount of drugs above "the amount indicated on the package label" — was Medicare's policy on "Discarded Drugs and Biologicals." (*See* Relator Ex. 33 at 5.) This policy prohibits *discarding* overfill and then seeking reimbursement for it. It does not address instances where entities *actually administer* it. One could have deduced from the Medicare policy on discarded drugs that overfill was free, and thus should not be billed even if administered. But one could alternatively, reasonably assume that by prohibiting overfill billing only when overfill is discarded, Medicare implicitly recognized that overfill can be billed when administered. As one court has recognized, the fact that CMS felt compelled to issue a rule to "clarify" its position on billing for administered overfill, *see* 75 Fed. Reg. at 73467, "suggest[s] there was some ambiguity before the rule was announced." *United States ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 70 (D. Mass. 2011). Thus, the Court starts with the understanding that the rules or regulations did not unequivocally prohibit billing for administered overfill.

Faced with this ambiguity, the undisputed evidence in the record shows that Fresenius believed — and its counsel advised — that administered overfill was reimbursable. (*See* Part III.A.) The record shows that, whether right or wrong, this interpretation was plausible because Fresenius and its counsel based its ongoing belief that overfill was reimbursable on among other things, the long history of overfill billing with what they reasonably believed was government

knowledge and acquiescence and the apparent widespread industry practice of overfill billing.

Since the 1990s, Fresenius has utilized overfill, billed Medicare for its administration, and disclosed this practice at varying opportunities. Each time the specter of overfill billing impermissibility reared its head, Fresenius and its counsel watched as the government declined to prosecute or even warn ESRD facilities that overfill was not reimbursable. During much of this time, Fresenius expressly or implicitly conveyed to the government that it was administering overfill and billing Medicare for it. All of this suggests that Fresenius had at least by 2005 developed the reasonable belief that overfill billing was permissible.

Relator argues that all this changed in 2005 when the Secretary declined to take overfill into account when setting reimbursement rates. According to Relator, the government's apparent acquiescence before 2005 is irrelevant to Fresenius's state of mind. Relator suggests that there is little evidence of the government's knowing acquiescence after 2005, and thus, according to Relator, Fresenius's belief that the government condoned overfill billing from 2005 through 2010 was reckless.

Relator is correct that evidence of Fresenius's disclosures to the government about its overfill billing practices seems to peter out after 2005, but the evidence is not entirely absent. For example, Fresenius was open about billing for overfill through the entire duration of the Corporate Integrity Agreement with OIG, from 2002 through 2008. In an attached document to a

2006 OIG audit, Fresenius expressly recognized that it was billing for Epogen overfill. And Fresenius did not hide that it was utilizing (and implicitly billing for) overfill in its SEC filings.[35] True, this evidence alone is far from sufficient to put to rest the question whether CMS knowingly acquiesced. None of these disclosures were directly to CMS, the reference to overfill billing in the audit document is essentially buried, and the SEC filings overfill disclosures are not entirely clear as they simply reference Fresenius's business model of utilizing Epogen overfill and separately note that Fresenius bills Medicare for administered Epogen. Thus, none of this evidence, or any other evidence in the record of government knowledge, supports Fresenius's bold claim that the "government's knowledge of the challenged conduct and its continued payment of claims negate the intent element of the FCA." (Def. Memo. Supp. Mot. Summ. J. at 22, Doc. 221-1.)

But the better question is whether *Fresenius's* belief that the government continued to knowingly acquiesce in Fresenius's overfill billing practices after 2005 was reckless. For purposes of the reasonableness of this belief, Fresenius's disclosures throughout the history of its overfill billing practices, and not just from 2005 through 2010, are at least relevant to understanding how Fresenius approached the question of overfill billing at each regulatory turn. *See Urquilla-*

[35] Fresenius also points to Fresenius's 2007 response to a subpoena in the *Woodard* case. (Def. Ex. 147.) The subpoena itself only requested documents "received, dated, referred to, or created at any time during the period of October 1, 2007 through December 31, 2004." (*Id.*) Thus, although Fresenius eventually responded to the subpoena, it is not clear whether its response disclosed that it was billing for administered overfill after 2004.

Diaz, 780 F.3d at 1060; *Burlbaw*, 548 F.3d at 951-52 ("Relators' evidence cannot be evaluated in a factual and legal vacuum."). When CMS declined to account for overfill in determining the Average Acquisition Cost or Average Sales Price, it expressly did so because of "operational infeasibility." CMS did not announce that its disregard for overfill was because it was free to the provider; CMS did not address in its methodology the cost of overfill to the provider at all. Thus, although Fresenius could have inferred from the reimbursement calculations that Medicare implicitly treated overfill as free, it was at least also plausible that the reimbursement methodology simply did not speak to whether overfill was free at all, and did not prohibit the overfill billing practices that by 2005 were well-known in industry and government. Indeed, to the extent Fresenius did not believe the Medicare rules about what units were reimbursable changed with the adoption of the Average Sales Price, this belief is consistent with the belief of CMS's corporate designee, Marc Hartstein. (*See* Hartstein Dep. at 49 (confirming that the adoption of the ASP methodology did not change CMS's policies about which units were reimbursable).) Evidence that Fresenius made no effort to hide its overfill administration billing practices after 2005 thus weighs against a finding of recklessness.

More importantly, however, the evidence is nearly entirely one-sided that the government in fact *did* understand dialysis clinics were administering and billing for overfill from 2005 through 2010, suggesting that Fresenius's belief that the government knew about overfill billing and acquiesced was reasonable, or at

least not grossly negligent. For example, CMS's corporate designee John Warren confirmed that CMS had "full knowledge of the fact that it was a regular practice that providers were billing for overfill." (2012 Warren Dep. at 116; *accord* Hartstein Dep. at 45 (confirming that as soon as he began working at CMS in 2009, he learned that ESRD clinics were using and billing Medicare for overfill).) Fresenius's two expert witnesses confirmed that CMS was aware of overfill billing. Brady Augustine, who was the former Senior Advisor to the CMS Administrator who oversaw ESRD issues testified, "It is my opinion that use and billing for overfill was widespread industry practice and known to CMS at all relevant times and that it was reasonable and proper for Fresenius to believe that it was not violating any rules against using or billing for overfill at all times prior to January 1, 2011." (Def. Ex. 36 ("Augustine Expert Report") at 21-22.) And Kevin McAnaney, former Chief of the Industry Guidance Branch of OIG, testified that there was a "consensus view among experienced health care counsel, industry participants, and regulators at the time" from 2003 through 2010 that overfill was properly billable. (Def. Ex. 40 ("McAnaney Report") at 1, 3.)

Relator offers scant evidence to the contrary. Relator first directs the Court to the fact that that in 2009, none of the dialysis companies provided data about overfill utilization or billing to the Secretary in connection with requests into their average acquisition costs. (Relator Resp. at 8, Doc. 230.) This evidence does not address one way or the other whether CMS believed dialysis facilities

were billing Medicare for overfill.[36] Relator next asserts that CMS did not "knowingly" reimburse providers for overfill usage because it did not know when it received a request for reimbursement whether the ESRD drug administered included some amount of overfill. (*See* Relator Reply at 15.) Relator relies on Hartstein's testimony in which he confirms that CMS did not make payment determinations based on whether overfill was included in the submission. (Relator Ex. 7 ("Hartstein Dep.") at 44-45.) This evidence is at best ambiguous about whether CMS knew providers were billing for overfill. And other evidence in the record shows that CMS in fact knew some of the submissions included overfill and thus, knew that by choosing to reimburse the claims it received, it was reimbursing for overfill. *See also United States ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 70 (D. Mass. 2011) ("In addition, until the rule took effect on January 1, 2011, CMS continued to pay claims for Medicare reimbursement irrespective of the inclusion of overfill.").

The only evidence in the record that arguably supports Relator's contention that the government did not know of a widespread, industry practice of billing for administered overfill is a statement in the 2010 proposed rule "that such inappropriate billing [for overfill] does not occur routinely." (Relator Resp. at 8, Doc. 230 (citing 75 Fed. Reg. 73467 (Nov. 29, 2010)).) This evidence, standing

[36] Relator also urges the Court to draw the inference that, because Fresenius did not report overfill in its cost reports when OIG stopped asking for that information, it was somehow purposefully concealing that it was utilizing and billing for overfill. This is not a reasonable inference. And Relator has offered no specific evidence suggesting that Fresenius, or any dialysis companies in the industry, were attempting to hide their overfill billing practices.

alone, does little to shore up Relator's contention that CMS was unaware of the widespread practice of overfill billing, particularly when compared to the weight of evidence showing CMS was in fact aware of this practice. But even if a jury determined based on this minimal evidence that CMS was not aware of a widespread industry practice of overfill billing, the record does not permit the inference that *Fresenius's* belief to the contrary was unreasonable.[37]

That Fresenius's belief about overfill billing was reasonable is further confirmed by evidence suggesting that others in the industry routinely engaged in overfill billing and expressly believed overfill billing was permissible. As noted above, Fresenius's two expert witnesses confirmed that overfill billing was a "widespread industry practice." And even Relator's own expert, Dr. James Alexander, agreed that it was "appropriate for Fresenius to use and bill for overfill as long as it [did] it on the same shift with the same patients and properly administer[ed] the exact amount of drug that the doctor want[ed]." (Def. Ex. 37 ("Alexander Dep.") at 293.) It is hard for Relator to argue that Fresenius was reckless in believing it could bill for overfill actually administered when Relator's own expert held the same belief. Relator offered no testimony from any witness suggesting that Fresenius's interpretation was unreasonable.

[37] It is also of little significance that some of Fresenius's disclosures only identified utilization of overfill, not Medicare billing. When Fresenius disclosed that it was utilizing overfill and that reduction in overfill amounts would affect its bottom line, the necessary implication was that Fresenius was also billing payors for the use of this overfill. And since Medicare was a major payor to Fresenius, it was not unreasonable for Fresenius to believe that by disclosing its overfill administration practices to OIG, for example, it was also making clear that Fresenius was billing Medicare for overfill administration.

Of course, simply acting in conformity with others in the industry does not absolve government contractors of FCA liability. The potential for regulatory capture is real, and it is not beyond the realm of possibility that a majority of contractors in an industry could submit false claims to the Government with the hope that, because the conduct occurs on a large scale, the Government, whether purposefully or not, would simply overlook such false claims. But under the distinct circumstances presented here, Fresenius and its counsel's interpretation, although perhaps ultimately wrong, was not unreasonable.[38]

This is also not a case of a defendant receiving the benefit of clear regulations or a clear, authoritative warning from the government that its conduct might be unlawful and failing to take appropriate action. *See K&R*, 530 F.3d at 983-84. As already explained, no publication with the force of law put providers on notice, *prior* to the 2011 rule, that billing for overfill administration was impermissible. Both CMS's corporate designee John Warren and Relator's own expert Dr. Alexander agreed with this assessment. (*See* 2012 Warren Dep. at 115-116; Alexander Dep. at 134.) And when CMS adopted the average sales price reimbursement methodology, CMS did not announce in any policy document or advisory statement that billing for overfill administration was thereafter prohibited, despite indisputably knowing that dialysis facilities were, at least at that time, billing for administered overfill. Indeed, Fresenius's CEO made this

[38] And it was certainly not unreasonable for Fresenius to assume, correctly as it turns out, *see below* Part V, that the "incident to" provisions expressly governing physician reimbursement did not apply to ESRD facilities.

clear in its objection to CMS's 2005 proposed rule, explaining to CMS in the context of Medicare reimbursement that "providers generally utilize the overfill amount to minimize cost and wastage," and that this practice was "a widely and accepted practice in the dialysis industry." (Relator Ex. 23.) In response, had CMS wanted to prohibit billing for administered overfill, it certainly could have done so directly, as it did in 2010.[39] This is not to say that an abundantly careful and independent attorney could not have determined that billing for administered overfill was inconsistent with general Medicare principles, or that CMS could have began enforcing this policy without adopting a subsequent regulation. But the record simply contains no clear, authoritative warning or regulatory directive from the government that administered overfill was not reimbursable.

The closest Fresenius got to a "warning" of any kind was the 2005 TrailBlazer document. This document was about "wastage." (Def. Ex. 201.) TrailBlazer, a Medicare fiscal intermediary, advised that, although providers could bill for wastage in some circumstances, they could not bill for wasted overfill (which Fresenius did not do). But the TrailBlazer document also seemed

[39] And as Fresenius's counsel argued at oral argument, even when CMS finally did expressly prohibit billing for administration of overfill, it's rule was prospective only. CMS announced the rule in 2010, and in response learned that providers were actively billing for administered overfill. Yet, there is no evidence that CMS or any fiscal intermediaries at that time investigated whether overfill billing was occurring, rejected requests for reimbursement for ESRD drugs on the basis that the requests included overfill, or sought to recover overpayments based on overfill billing, which CMS could have presumably done.

to advise providers not to bill for *administered* overfill either. This TrailBlazer document does not tip the scales in favor of a finding of recklessness.

As an initial matter, although the TrailBlazer document, and more importantly, Fresenius's attorney's reaction to the document, is certainly relevant to the question of recklessness, the document is several steps removed from an authoritative interpretation of CMS rules or regulations. As Fresenius points out, as a fiscal intermediary, TrailBlazer had "limited authority to adopt local coverage determinations or local medical review policies applicable to claims they process, these policies are not binding on Medicare." (Def. Resp. at 18, Doc. 232 (citing Def. Ex. 233 ("Alexander Dep.") at 133).) *See also Heckler v. Community Health Serv.*, 467 U.S. 51, 64, 66 (1984) (recognizing that fiscal intermediaries are "not in the business of making policy"); *Monongahela Valley Hosp., Inc. v. Sullivan*, 945 F.2d 576, 589 (3d Cir. 1991) (rejecting the plaintiff's contention that it reasonably relied on a policy statement of a fiscal intermediary "[b]ecause a fiscal intermediary can neither definitively interpret regulations nor make policy pronouncements"). And this document is apparently not even a TrailBlazer official policy statement. (*Compare with* Def. Ex. 221 (2010 TrailBlazer ESRD Manual); Def. Ex. 232 (2008 ESRD TrailBlazer Manual).) TrailBlazer's official policy statements, TrailBlazer's ESRD Manuals, do not contain a prohibition against billing for *administered* overfill.

Nonetheless, although not authoritative, the 2005 document certainly rang some alarm bells. Fresenius's CEO believed this policy was a "major issue."

Fresenius's in-house counsel felt it deserved a working group to consider and respond to this policy. And Fresenius's outside counsel recommended further inquiry by contacting TrailBlazer for a status update, and if necessary, going to CMS to address the issue.[40] A reasonable jury could infer from this record that Fresenius did not obtain a status update from TrailBlazer and did not raise the issue with CMS. Relator thus argues that Fresenius's failure to take these steps as its attorney had recommended, in combination with other evidence including evidence that in other contexts Fresenius went straight to government regulators when it had concerns about its compliance, is sufficient to support a finding of recklessness.

Relator's argument misses the mark because he fails to emphasize the lack of real concern Fresenius's counsel conveyed about the TrailBlazer document and disregards undisputed evidence in the record that this TrailBlazer document was never memorialized into an official policy prohibiting ESRD clinics from billing for administered overfill. While it is true that Fresenius's outside counsel Larri Short recommended obtaining a "status update" with TrailBlazer, she further advised that the TrailBlazer document was inconsistent with CMS rules, which

[40] Relator slightly overstates the record when he asserts that Fresenius's counsel advised Fresenius to consult CMS regarding the TrailBlazer policy. Fresenius's counsel instead noted that the policy "merits CMS intervention to address the complex realities of multi-dosing out of single-dose vials and the inevitability of overfill usage when dialysis centers and physicians consistently do so." (Realtor Ex. 30. at 1.) But the attorney further indicated that Fresenius would "need to know with certainty whether TrailBlazer is applying or intends to begin applying the policy to [its] ESRD facilities" before Fresenius has a "reasoned dialogue" with CMS about this policy. (*Id.* at 2.) While it may be dancing on the head of a pin, it is nonetheless inaccurate to state that Fresenius was advised to "take the issue directly to top officials at CMS in order to clarify whether the restriction on billing for overfill applied to dialysis providers." (Relator Resp. at 32, Doc. 230.)

only prohibited billing for overfill when it is discarded and did not address overfill as administered. She also advised that the document, which she received in connection with her non-nephrologist physician client, did not clearly apply to ESRD facilities. And neither she, nor any attorney reviewing this policy, advised Fresenius to stop billing for overfill actually administered. Thus, while the TrailBlazer policy presented some degree of concern, Fresenius's counsel indicated that the threat level was relatively low. In light of this evidence, Fresenius's reaction, although insufficient, was not reckless.

Moreover, the uncontroverted evidence shows that TrailBlazer never in fact applied this overfill administration policy to ESRD facilities. The only official TrailBlazer ESRD policies in the record are silent as to billing for administered overfill. Thus, Fresenius's understanding that TrailBlazer did not intend for its policy to apply to ESRD facilities was not only reasonable, but accurate. And a subsequent communication from Fresenius's outside counsel in March 2006 confirmed that under CMS rules, while overfill cannot be billed if it is "wasted," it can be billed if it is "actually utilized to fill a prescription." (Def. Ex. 198.) Under these circumstances, Fresenius's conduct — failing to get a "status update" from a government contractor or failing to obtain guidance from CMS regarding a policy that, as far as Fresenius's counsel was concerned, did not conform to CMS

regulations and ultimately was never applied to ESRD clinics — was not reckless.[41]

If any doubt remains whether Fresenius acted recklessly, additional evidence in the record showing how serious Fresenius considered its compliance with Medicare rules and regulations puts this doubt to rest. For example, in 2002, in connection with a Corporate Integrity Agreement ("CIA"), Fresenius explained to the OIG representative Nicole Caucci that some of its clinics may have billed for more overfill than was in a vial. Fresenius then set up an escrow account devoted to funds associated with overfill billing and promptly developed new procedures to ensure that excess billing was not occurring. This type of good faith effort to comply with Medicare billing requirements regarding overfill led Caucci to find that Fresenius was "forthcoming" and "fully disclosed" it was utilizing and billing Medicare for overfill during the duration of the CIA *from 2002 through 2008*. In fact, Caucci herself stated that Fresenius took "the issue of overfill recovery pretty seriously." (Def. Ex. 106 at 1.) And Brady Augustine, then Senior Advisor to the CMS Administrator, agreed that Fresenius had been a

[41] The Relator did not argue that a 2008 published article, warning providers of the dangers of overfill billing, (Def. Ex. 196), served as a warning to Fresenius. But even if the Court considered this article, and Fresenius's response, (Def. Ex. 9, ("Kembel Decl.") ¶ 65 and Ex. AA), the Court would not change its decision. The article is even less authoritative and less on-point than the TrailBlazer document. The article did not, for example, address the significance of the Average Sales Price methodology, and did not suggest, as Relator does, that the way CMS determines the reimbursement amount is the lynchpin to understanding the impermissibility of overfill billing. Moreover, the only evidence in the record addressing how Fresenius handled this article shows that Fresenius's lawyers viewed the article as raising Anti-Kickback concerns, and simply did not appreciate the risk that Fresenius was taking. Perhaps this was negligent, but Fresenius's response to this article does not tip the scales in favor of a plausible finding of recklessness.

"good corporate partner and has imposed quite restrictive policies on itself." (*Id.*) This and similar conduct[42] contradicts a finding of recklessness as to ESRD drug rules. *See Urquilla-Diaz*, 780 F.3d at 1062 (considering the defendant's efforts to comply with the Rehabilitation Act as evidence that the defendant took its obligations seriously).

Relator's argument and evidence boils down to this: Fresenius had at its disposal the information it needed to come to the conclusion that billing for overfill was impermissible. (*See* Relator Memo. L. Supp. Mot. Summ. J. at n.13, Doc. 217-1.) It knew physicians could not bill for drugs they received for free. It was aware of general Medicare rules and regulations which implicitly recognize others must incur an expense before requesting reimbursement from the government. And it knew the ASP methodology did not factor in overfill. Thus, according to Relator, Fresenius should have connected these dots, and deduced — as TrailBlazer did, as Relator did, and ultimately as the Court did — that billing for overfill actually administered was not permitted.

[42] The record contains other evidence that Fresenius took its Medicare billing requirements seriously. For example, during the early 2000s when the CDC changed its reentry recommendations, Fresenius executives met with CMS, consulted its attorneys, and modified its reentry protocols to ensure its conduct complied with the CDC and CMS requirements. And as soon as CMS determined that reentry into Zemplar vials was prohibited, Fresenius stopped such reentry and ceased billing for overfill. Although this evidence is in a slightly different context, it is nonetheless evidence from which a reasonable jury could infer that Fresenius generally took Medicare billing seriously, particularly when it came to reentering vials and extracting additional medicine, including overfill, for administration and reimbursement. *See K&R*, 530 F.3d at 984 (rejecting a finding of recklessness based in part on evidence that the defendant brought to the agency's attention, "albeit for a somewhat different issue," facts regarding the refund that later became the basis for the FCA claim).

Perhaps Relator is correct. Fresenius's exploitation of silence or ambiguity in the Medicare rules or regulations, capitalizing on a loophole in the regulatory fabric, certainly has an unsettling dimension to it. The Court agrees with Relator that "as the recipient of substantial largesse from the Government," Fresenius had an obligation to act with integrity and not abuse its position as government contractor. And the Court credits Relator's position that the presumption in Medicare reimbursement practices is that a provider does not bill for something it received for free. The record thus supports a reasonable inference that Fresenius negligently failed to recognize the relationship between various Medicare principles, rules and regulations, and failed to properly investigate whether overfill was a reimbursable drug product or instead no different than a free sample. Also based on this record, a jury could decide that sophisticated companies such as Fresenius were not blindsided when CMS proposed to prohibit overfill billing. Indeed, issues involving overfill extraction, administration, and billing had bubbled to the surface time and again for decades — in the context of patient safety and reentry protocols, alleged kickbacks and improper marketing, wastage, and of course, billing for overfill administration. And viewed in the light most favorable to Relator, Fresenius knew free items were not reimbursable.

Nonetheless, Fresenius's failure to connect the dots — to fully appreciate that overfill was to be treated just like a free sample for reimbursement purposes — although arguably negligent, does not support a finding of recklessness based

on this record. Instead, the record shows that Fresenius adopted a plausible interpretation of the Medicare rules and regulations, consistent with its communications with OIG and CMS and with some in the industry (including Relator's own expert). CMS could presumably have timely and successfully attempted to recover overpayments based on overfill reimbursement prior to 2011. But to expose Fresenius to treble damages in an FCA action would only be appropriate if Fresenius recklessly disregarded or alternatively fraudulently with intent disregarded the fact that overfill was simply not reimbursable. On this record, no reasonable jury could make such a finding.

2. Actual Knowledge

As the Court finds the record insufficient to support a finding of recklessness, it does not need to decide whether Relator can satisfy the higher evidentiary burden of proving that Fresenius had actual knowledge that overfill billing was impermissible. The Court nonetheless briefly rejects Relator's argument on actual knowledge. As just stated, the Court agrees that a reasonable jury could infer that Fresenius knew individual pieces of information. For example, the record contains evidence that Fresenius knew the Secretary did not factor overfill in when determining the reimbursement amount for Epogen or Zemplar under the average acquisition cost or ASP methodology. (*See supra* Part III.B.3.) The record also contains evidence that Fresenius knew *physicians* could not bill for drugs unless they incurred an expense for the drugs, and that even ESRD clinics could not bill for items such as free samples. (2012 Kembel Dep. at

105.) But the record contains no evidence Fresenius actually knew that for reimbursement purposes, it should treat overfill as free and thus could not seek Medicare reimbursement for it. On the contrary, the only evidence in the record suggests that Fresenius always understood — even if mistakenly — that it incurred an expense for overfill, and never believed that CMS disagreed with this assessment. (*See supra* Part III.A).[43] Fresenius simply did not appreciate that when Medicare declined to factor overfill into its reimbursement calculation for Epogen and Zemplar, ESRD facilities should treat overfill as free and not bill Medicare for its administration. The record does not support a finding of actual knowledge.

C. Conclusion

As Relator has failed to identify sufficient evidence in the record from which a reasonable jury could infer that Fresenius knowingly or recklessly submitted a false claim when it requested reimbursement for administered Epogen or Zemplar overfill, Fresenius's Motion for Summary Judgment is **GRANTED**.

V. RELATOR'S MOTION FOR PARTIAL SUMMARY JUDGMENT

Although the Court's decision above compels the Court to deny Relator's Motion for Partial Summary Judgment, the Court finds it necessary to briefly

[43] Relator seems to argue that the 2005 TrailBlazer article put Fresenius on notice that billing for overfill was impermissible, thus allowing a reasonable jury to infer actual knowledge. But "actual knowledge" means what it says — here, that Fresenius actually knew it could not bill for overfill because overfill was considered "free." The evidence shows that Fresenius viewed the TrailBlazer article, based on advice of counsel, as taking a policy position inconsistent with Medicare rules and inapplicable to dialysis facilities like Fresenius's.

address Relator's Motion. (Doc. 217.) Relator's Motion only addresses Zemplar and argues, for the first time, a slightly different theory of liability. Rather than relying primarily on the ASP methodology to prove falsity, Relator argues that the "incident to" rules — which more clearly prohibit physicians from billing for items they receive at no expense — support the conclusion that Fresenius's billing for Zemplar overfill was impermissible. Relator then points to evidence that Fresenius was familiar with the incident to rules and their implications.

The basic premise upon which Relator rests his motion is the mistaken assertion that Zemplar reimbursement is "governed" by the "incident to" billing rules, which allow reimbursement only for incurred expenses. (*See* Doc. 217-1 at 2 ("Zemplar is not specifically provided by the Medicare Act, but rather always has been available under a provision that generally extends coverage for drugs that are not usually self-administered but provided 'incident to a doctor's services.'") (citing 42 U.S.C. § 1395x(s)(2)(A)).) Relator argues that according to Chapter 15 of the Medicare Benefit Policy Manual, to satisfy the "general requirements for coverage under the incident to provisions . . . [a] drug or biological must be of a form that is not usually self-administered by the physician . . . and [t]he charge, if any . . . *must represent an expense to the physician*." (Relator Ex. 3.) Thus, if the "incident to" provisions govern Zemplar reimbursement, physicians who seek reimbursement for Zemplar can do so only to the extent the charge represents an expense to the physician.

But as Fresenius correctly notes, this case does not involve physician-administered drugs. According to the Medicare Benefit Policy Manual, the "incident to" provision, codified at 42 U.S.C. § 1395x(s)(2)(A), addresses "services and supplies . . . furnished as an incident to a *physician's* professional service." 42 U.S.C. § 1395x(s)(2)(A) (emphasis added). The "incident to" rules that flow from this section do not govern separately billable drugs administered by renal dialysis facilities. *See also* 42 U.S.C. § 414.900(b) (providing as separate examples of drugs that are not paid on a cost or prospective payment system basis "[d]rugs furnished incident to a physician's service" and "separately billable drugs at independent dialysis facilities not under the ESRD composite rate"). Indeed, Relator essentially recognized this fact when, in his briefing on the parties' first cross-motions for summary judgment, he stated, "[T]he unremarkable proposition that the 'incident to' rules do not apply to dialysis providers . . . has absolutely no relevance here." (Doc. 122 at 13; *see also* 2013 Relator Resp. Def. SUMF at 117-118, Doc. 120 ("The prohibition on dialysis providers billing Medicare for overfill is not found within the incident to rule."). *See also* 75 Fed. Reg. 73170, 73469 (Nov. 29, 2010) (recognizing that the benefit category for a drug or biological — whether it is, for example, reimbursed under the "incident to" rules — is irrelevant to CMS's policy for ASP calculations, which serve as the basis for prohibiting overfill billing).

Relator backtracks from that recognition now. He argues that pursuant to a separate Medicare guideline, any drug that is not specifically identified by name

in the statute is governed by the "incident to" rules. The guidance upon which Relator relies is found in Chapter 11 of the Medicare Benefit Policy Manual, which specifically addresses ESRD. (Relator Ex. 6, Doc. 217-9 at 6.) This section provides:

> Generally, except for those categories of drugs and biologicals for which coverage is ***specifically provided by the statute***, e.g. EPO and drugs used as immunosuppressive therapy, drugs and biologicals are covered only if all of the following requirements are met . . . (e) They meet all the general requirements for coverage of items as incident to a physician's service.

(*Id.* (emphasis added).)

Relator's reliance on this guidance is misplaced for two reasons. First, this excerpt from the Policy Manual addresses a "general[]" principle followed simply by a nonexclusive list of examples of drugs specifically provided by the statute.[44] As such, it (a) does not foreclose the possibility that a drug for which coverage is not specifically provided in the statute would nonetheless be excepted from the general requirements listed therein and (b) recognizes that "EPO and drugs used as immunosuppressive therapy" are not the only drugs that fall within this category. At best, this evidence is ambiguous as to whether Zemplar is reimbursed under the "incident to" rules.

Second and more importantly, while Zemplar is not called out by name, Zemplar coverage *is* specifically provided by the statute. Section 1395rr(b)(13)(A) provides for reimbursement of "separately billable [ESRD] drugs." 42 U.S.C. § 1395rr(b)(13)(A). And the parties have previously agreed that Zemplar (and

[44] Relator omits the word "generally" from its selected quotation from the Policy Manual.

Epogen) are separately billable drugs (as opposed to drugs billed under a composite rate). (*See* Doc. 141 ¶¶ 1, 2; Doc. 141 ¶¶ 1-4, 7.) CMS has expressly recognized that drugs covered by statute are not the same as those furnished incident to a physician's service, and the phrase "drugs specifically covered by statute" includes vitamin D injections (Zemplar).

> Currently covered Medicare Part B drugs generally fall into three categories: Drugs furnished incident to a physician's service, drugs administered via a covered item of durable medical equipment (DME), and drugs covered by statute. . . . ***Drugs specifically covered by statute include*** — immunosuppressive drugs; hemophilia blood clotting factor; certain oral anti-cancer drugs; oral anti-emetic drugs; pneumococcal, influenza and hepatitis B vaccines; antigens; erythropoietin for trained home dialysis patients; certain other drugs separately billed by end-stage renal disease (ESRD) facilities (for example, iron dextran, ***vitamin D injections [Zemplar])***; and osteoporosis drugs.

70 Fed. Reg. 39022, 39023 (July 6, 2005) (emphasis added); *see also* 42 C.F.R. § 405.517 (separately identifying drugs "furnished incident to a physician's service" and drugs "furnished by an independent dialysis facility that [are] not included in the ESRD composite rate"). (*See also* Def. Ex. 222 ("Carriers and intermediaries must not apply incident to requirements to services having their own benefit category [under § 1861].").) Moreover, this Court has already decided that the "incident to" provisions apply to physician provision of services, not dialysis centers. *See United States ex rel. Saldivar v. Fresenius Medical Care Holdings, Inc.*, 972 F. Supp. 2d 1339, 1351 n.13 (N.D. Ga. 2013).

In his reply brief, Relator also suggests that the testimony of CMS's corporate designee, Marc Hartstein, clears up any confusion that Zemplar is

reimbursed under the incident to rules. Hartstein was asked whether it was his understanding that "end stage renal disease facilities [were] billed under the incident to rules." (Hartstein Dep. at 28-29.) He responded that he believed "separately payable Part B drugs were billed under the incident to rules." (*Id.* at 29.) Putting aside that Relator himself agrees that Epogen — a separately payable Part B drug — when dispensed at ESRD facilities was not billed under the incident to rules, Hartstein's testimony simply reveals his own legal interpretation of the relevant Medicare rules and regulations. Hartstein's testimony does not trump the Court's authority to interpret the law. Moreover, Relator's own expert witness, Dr. Alexander, Testified that "incident-to is not a section that . . . applies to ESRD." (Alexander Dep. at 110.) The Court finds no basis to reconsider its decision that Zemplar and Epogen were not reimbursed under the incident to rules.[45]

For these reasons, Relator's underlying premise is wrong. Zemplar is specifically covered by statute and not subject to the incident to rules. As this appears to the be sole basis for arguing for a different outcome as to Zemplar, the Court **DENIES** Relator's Motion for Partial Summary Judgment [Doc. 217].

[45] Likwise, David Kembel's testimony regarding the difference between Epogen, which he stated was "reimbursed by statute" and Zemplar, which he apparently believed was not, does not alter the Court's decision. Kembel's testimony on this topic is unclear. And even if Kembel understood that Zemplar was not "reimbursed by statute," there is no evidence Kembler understood that Zemplar was reimbursed under the incident to rules.

VI. CONCLUSION

For years, Fresenius, the nation's largest owner of outpatient renal dialysis facilities, capitalized on overfill — the extra amount of medicine, over the labeled amount, contained in individual vials of expensive End Stage Renal Dialysis ("ESRD") drugs. The purpose of overfill was ostensibly to account for the difficulty technicians had in extracting the entire amount of medicine contained in a vial. Fresenius's technicians, and many others in the industry, honed their ability to extract not only all of the labeled amount of medicine in the vial, but the overfill as well. Fresenius then administered this overfill as part of its treatment and billed its payors, including Medicare, for this administration.

The Court previously interpreted the rules and regulations governing Medicare reimbursement generally and ESRD drugs in particular, and held that billing Medicare for overfill actually administered was impermissible from 2006 through 2010. Fresenius's request for reimbursement based on this overfill was inconsistent with Medicare rules and underlying policies and thus constituted a "false" claim for purposes of the False Claim Act, 31 U.S.C. § 3729 et. seq.

The question before the Court now on the parties' second cross-motions for summary judgment is whether Fresenius "knowingly" submitted such false claims. And as explained above, the overwhelming evidence shows that Fresenius reasonably interpreted ambiguous Medicare rules, relied on the advice of its counsel, reasonably believed that at all times the Government knew it was billing for overfill and condoned such billing, and acted in conformity with others

in the industry. Fresenius may have been negligently unaware that overfill was considered "free" and could not be billed, and negligently failed to inquire when it learned that at least some in the industry believed billing for overfill actually administered was impermissible. But to hold Fresenius liable under the False Claims Act, Fresenius must be more than simply negligent. This record does not support such a finding. Accordingly, the Court **GRANTS** Defendant's Motion for Summary Judgment [Doc. 221] and **DENIES** Relator's Motion for Partial Summary Judgment [Doc. 217]. This action is **DISMISSED.** The Clerk is **DIRECTED** to enter judgment in favor of Defendant and **CLOSE** the case.

IT IS SO ORDERED this 30th day of October, 2015.

Amy Totenberg
United States District Judge